

EPA Registration Jacket 72642-10

Vol. 1



Elanco Animal Health

2500 Innovation Way
Greenfield, IN 46140
317.276.2000

February 20, 2013

U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Attn: Mr. Mark Suarez, Project Manager

Subject: Notification of Final Printed Labeling per PR Notice 98-10

Product: Cheristin™ for cats [EPA Reg. No. 72642-10]

Dear Mr. Suarez,

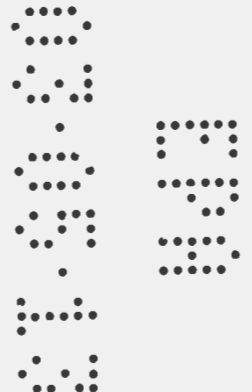
As instructed in the letter of issuance of the registration approval of this product, please find attached two copies of the finished product labeling for Chersitin™ for cats.

A fully executed EPA Form 8570-1 is also attached to this letter.

If you have any questions or comments, please feel free to contact me at your earliest convenience. If I cannot be reached, please contact Cory Herr, Director of U.S. Regulatory Innovation, at (317) 651-2776 or at herr_cory_t@elanco.com.

Sincerely,

Aaron Johnson, DVM, MS
U.S. Regulatory Affairs
Elanco Animal Health
Office: 317-276-4021
Fax: 317-277-4167
Email: ajohnson@elanco.com





United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72642-10	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Elanco Animal Health / Cheristin for cats	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly & Company 2500 Innovation Way, P.O. Box 708, Greenfield, IN 46140 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated January 17 2013
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt.	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Aaron Johnson	Title Principal Consultant	Telephone No. (Include Area Code) 317-276-0421
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Principal Consultant, Regulatory Affairs	
4. Typed Name Aaron Johnson	5. Date February 20, 2013	

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

Cheristin™
for cats
Elanco™

Cheristin™ for cats

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SHD86355AMC

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

EPA Reg. No. 72642-10

EPA Est. No. 87859-IL-001

Elanco and Cheristin are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

CA4590

Cheristin™
for cats

Elanco™

TOPICAL
APPLICATOR

6

Cheristin™
for cats

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated 11/17/13



4

Elanco™

ACTIVE INGREDIENT
Sphinetram (CAS# 187166-40-1 & 187166-15-0), 11.2%
OTHER INGREDIENTS.....88.8%
TOTAL 100.0%
CONTENTS 6 - 0.026 fl oz (0.77 ml) applicator
SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE
PREVENTION AND TREATMENT OF FLEA INFESTATIONS

sphinetram

Cheristin™
for cats

NOT REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated 11/17/13

TOPICAL
APPLICATOR
6

Cheristin™
for cats

Elanco™

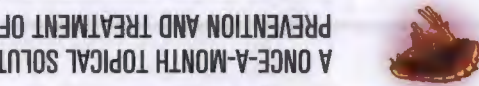
KEEP OUT OF REACH
OF CHILDREN
CAUTION

TOPICAL APPLICATION

ONCE-A-MONTH

1

FAST ACTING - STARTS
KILLING FLEAS IN 30 MIN

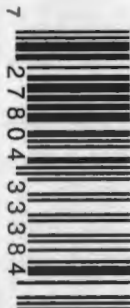




Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

Cheristin™
for cats
Elanco.

Cheristin™
for cats
Elanco.



3

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash. Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SH086355AMA

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

CA4590

EPA Reg. No. 72842-10
EPA Est. No. 87859-IL-001
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Cheristin™
for cats
Elanco.



TOPICAL
APPLICATOR

1

Cheristin™
for cats
spinetoramin

A ONCE-A-MONTH TOPICAL SOLUTION
FOR THE PREVENTION AND TREATMENT
OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER

ACTIVE INGREDIENT

Spinetoramin (CAS# 187166-40-1 & 187166-15-0)	11.2%
OTHER INGREDIENTS	88.8%
TOTAL	100.0%

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT
CONTENTS 1 - 0.026 fl oz (0.77 ml) applicator

Elanco.

**FAST ACTING -
STARTS KILLING
FLEAS IN 30 MIN.**

ONCE-A-MONTH

**TOPICAL
APPLICATION**

**KEEP OUT
OF REACH
OF CHILDREN
CAUTION**



Cheristin™ for cats spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION
FOR THE PREVENTION AND TREATMENT
OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 &

187166-15-0].....11.2%

OTHER INGREDIENTS.....88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC
ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.

2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)
6. Discard empty applicator tube in the trash.



Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-10
EPA Est. No. 87859-IL-001

Cheristin is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

CA4590

PA086355AMX



	1	2	3	4	5	6
7	8	9	10	11	12	13
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21	22	23	24	25	26	27
28	29	30	31			

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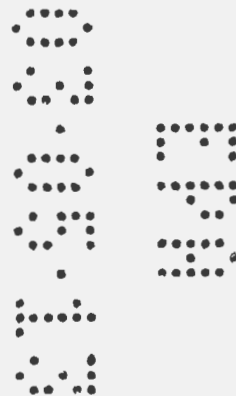
Cheristin is a trademark owned or licensed by
Eli Lilly and Company, its subsidiaries or affiliates.

Place stickers on your calendar as a reminder to apply
Cheristin for cats only to cats and kittens 8 weeks of
age and older

Visit www.CheristinForCats.com to sign up and receive
an email reminder from your cat
when it is time to receive
Cheristin for cats.



79910



Place sticker on your calendar
as a reminder to apply
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	1	2	3	4	5	6
7	8	9	10	11	12	13
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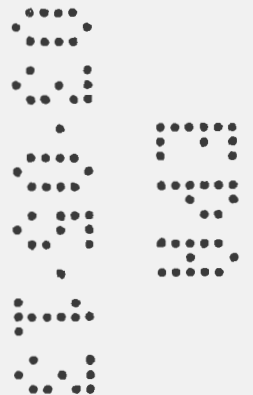
Visit www.CheristinForCats.com to
sign up and receive an email
reminder from your cat when it
is time to receive Cheristin for cats.

Cheristin is a trademark owned or
licensed by Eli Lilly and Company,
its subsidiaries or affiliates.

CA4390
EP085371A1A



79909



Cheristin™
for cats

spinetoram 11.2%

Only for Cats and Kittens
8 weeks of age and older
0.026 fl oz

EPA Reg. No 72642-10

CAUTION

Keep Out of Reach of Children
Read Entire Label Before Use

2D
Data
Matrix

CA4590

Elanco™

79906
FL086371AMB

Lot No.

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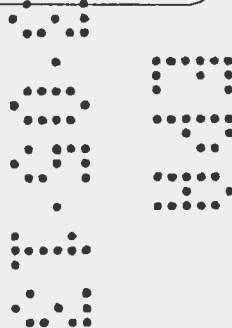
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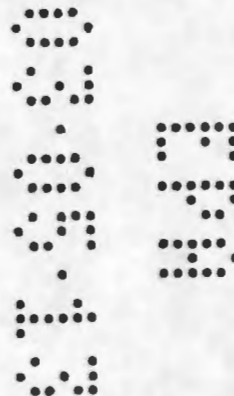
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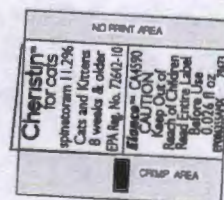
79905
FL086371AMA

Lot No. _____



EPA

03-05-13



Manufactured for
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A Division of Eli Lilly and Company
Indianapolis, IN 46285

Elanco

Cheristin™
for cats

Cheristin™ for cats

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

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SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

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TOPICAL
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ACTIVE INGREDIENT
Sphenotram (CAS# 187166-40-1 & 187166-15-0), 11.2%
OTHER INGREDIENTS 88.8%
TOTAL 100.0%
SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT
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EIGHT WEEKS OF AGE AND OLDER

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE
PREVENTION AND TREATMENT OF FLEA INFESTATIONS
sphenotram
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Cheristin™
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TOPICAL
APPLICATOR
6

KEEP OUT OF REACH
OF CHILDREN
CAUTION

TOPICAL APPLICATION

ONCE-A-MONTH



FAST ACTING - STARTS
KILLING FLEAS IN 30 MIN.

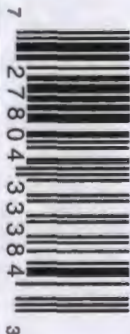




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It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash. Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SH086355AMA

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

EPA Reg. No. 72842-10

EPA Est. No. 87869-IL-001

Elanco and Cheristin are trademarks owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

Cheristin[™]
for cats **Elanco.**

CA4590



TOPICAL
APPLICATOR



Cheristin[™]
for cats
spinetoram

**FAST ACTING -
STARTS KILLING
FLEAS IN 30 MIN.**

ONCE-A-MONTH

**TOPICAL
APPLICATION**

**KEEP OUT
OF REACH
OF CHILDREN
CAUTION**

A ONCE-A-MONTH TOPICAL SOLUTION
FOR THE PREVENTION AND TREATMENT
OF FLEA INFESTATIONS

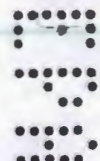
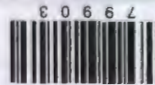
ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER

ACTIVE INGREDIENT

Spinetoram (CAS# 187166-40-1 & 187166-15-0)	11.2%
OTHER INGREDIENTS	88.8%
TOTAL	100.0%

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS
READ ALL DIRECTIONS BEFORE USING THIS PRODUCT
CONTENTS 1 - 0.026 fl oz (0.77 ml) applicator

Elanco.



Cheristin™ for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION
FOR THE PREVENTION AND TREATMENT
OF FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS
EIGHT WEEKS OF AGE AND OLDER

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 &
187166-15-0].....11.2%

OTHER INGREDIENTS.....88.8%
TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC
ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.

2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)
6. Discard empty applicator tube in the trash.



Monthly application is recommended to prevent and treat flea infestations. Cheristin for cats starts working in 30 minutes and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-10
EPA Est. No. 87859-IL-001

Cheristin is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.

CA4590

PA086855AMX



	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

Place stickers on your calendar as a reminder to apply Cheristin for cats only to cats and kittens 8 weeks of age and older

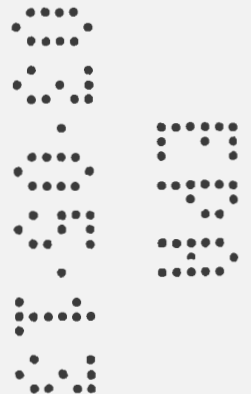
Visit www.CheristinForCats.com to sign up and receive an email reminder from your cat when it is time to receive Cheristin for cats

CA41590
EP096371A8B

Cheristin is a trademark owned or licensed by Eli Lilly and Company, its subsidiaries or affiliates.



79910



Place sticker on your calendar
as a reminder to apply
Cheristin for cats only to cats
and kittens 8 weeks of age and older.



	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

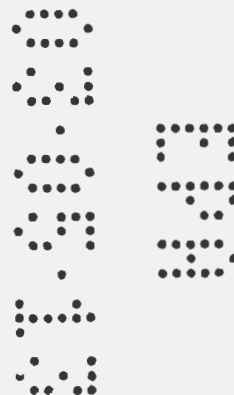
Visit www.CheristinForCats.com to
sign up and receive an email
reminder from your cat when it
is time to receive Cheristin for cats.

Cheristin is a trademark owned or
licensed by Eli Lilly and Company,
its subsidiaries or affiliates.

CAA590
EP086371AAM



79909



Cheristin™
for cats

spinetoram 11.2%

Only for Cats and Kittens
8 weeks of age and older
0.026 fl oz

EPA Reg. No 72642-10

CAUTION

Keep Out of Reach of Children
Read Entire Label Before Use

2D
Data
Matrix

CA4590

Elanco™

79906
FL086371AMB

Lot No.

Cheristin™
for cats

spinetoram 11.2%

Only for Cats and Kittens
8 weeks of age and older
0.026 fl oz

EPA Reg. No 72642-10

CAUTION

Keep Out of Reach of Children
Read Entire Label Before Use

2D
Data
Matrix

CA4590

Elanco™

79906
FL086371AMB

Lot No.

Cheristin™
for cats

spinetoram 11.2%

Only for Cats and Kittens
8 weeks of age and older
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Matrix

CA4590

Elanco™

79906
FL086371AMB

Lot No.

Cheristin™
for cats

spinetoram 11.2%

Only for Cats and Kittens
8 weeks of age and older
0.026 fl oz

EPA Reg. No 72642-10

CAUTION

Keep Out of Reach of Children
Read Entire Label Before Use

2D
Data
Matrix

CA4590

Elanco™

79906
FL086371AMB

Lot No.

Cheristin™
for cats

spinetoram 11.2%

Only for Cats and Kittens
8 weeks of age and older
0.026 fl oz

EPA Reg. No 72642-10

CAUTION

Keep Out of Reach of Children
Read Entire Label Before Use

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Data
Matrix

CA4590

Elanco™

79906
FL086371AMB

Lot No.

Cheristin™
for cats

spinetoram 11.2%

Only for Cats and Kittens
8 weeks of age and older
0.026 fl oz

EPA Reg. No 72642-10

CAUTION

Keep Out of Reach of Children
Read Entire Label Before Use

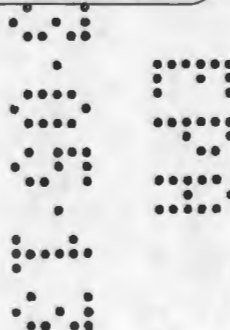
2D
Data
Matrix

CA4590

Elanco™

79906
FL086371AMB

Lot No.



Cheristin™
for cats
spinetoram 11.2%

Only for Cats and Kittens
8 weeks of age and older

0.026 fl oz
EPA Reg. No 72642-10

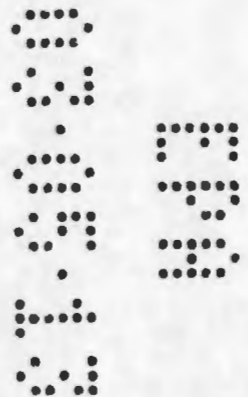
CAUTION
Keep Out of Reach of Children
Read Entire Label Before Use

Elanco™

2D
Data
Matrix CA4590

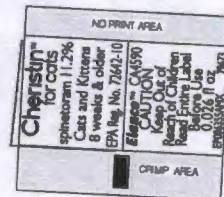
79905
FL086371A/MA

Lot No.



EPA

03-05-13



Material Sent for Data Extraction

Reg. # 72692-10

Description: ABN

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated _____

☐ Notification Dated May 6 2013

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: 476524

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Samantha Hulkower

Phone: 703-603-0693 Division: RD

Date: May 6 2013



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION PREVENTION

Mr. Aaron Johnson
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46410

MAY 06 2013
NOTIFICATION

NOTIFICATION
MAY 06 2013

Subject: Notification of primary brand name change
EPA Registration Number: 72642-10
Decision: 476524

Dear Mr. Johnson:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration (PRN)98-10 dated February 12, 2013, for the abovementioned product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the actions requested fall within the scope of PRN 98-10. The label submitted with the application has been stamped "Notification" and will be placed in our records.

If you have any questions regarding this letter, please Samantha Hulkower at (703) 603-0683 or Hulkower.Samantha@epa.gov.

Sincerely,

Mark Suarez
Product Manager 13
Insecticide Branch
Registration Division (7505P)

Enclosures: Copy of Label Stamped "Notification"



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72642-10	2. EPA Product Manager Mark Suarez	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Elanco Animal Health / Cheristin for cats	PM# 13	
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly & Co. 2500 Innovation Way, P.O. Box 708, Greenfield, IN 46140 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of a PRIMARY BRAND NAME

See additional page for further explanation

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Aaron Johnson	Title Principal Consultant	Telephone No. (Include Area Code) 317-276-4021
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Principal Consultant, Regulatory Affairs	
4. Typed Name Aaron Johnson	5. Date February 12, 2013	



Elanco Animal Health

2500 Innovation Way
Greenfield, IN 46140
317.276.2000

February 12, 2013

U.S. Environmental Protection Agency
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
Room S4900, One Potomac Yard
2777 Crystal Drive
Arlington, VA 22202

Attn: Mr. Mark Suarez, Project Manager

Subject: Notification of primary brand name per PR Notice 98-10

Product: Spinetoram 11.2% Cat [EPA Reg. No. 72642-10]

Dear Mr. Suarez:

On behalf of Elanco Animal Health, I am submitting for your review this Notification to add the **primary brand name** to the subject product. This addition of the new brand name **Cheristin™ for cats** is being done in compliance with the conditions outlined in PRN 98-10.

In addition to this letter, the Notification is comprised of:

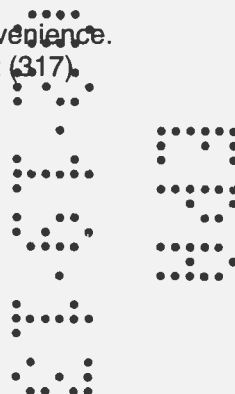
- A fully executed Application for Pesticide Registration (EPA form 8570-1)
- Certification statement (included with the 8570-1 form)
- One copy of the stamped approved label dated January 17, 2013
- A copy of the draft label with the changes clearly marked
- A copy of the label containing the new primary brand name

Additionally, Elanco would like to notify EPA of two additional changes to the label. First, the product registration numbers have been changed from 72642-RN to 72642-10, as directed by the approval notice dated January 17, 2013. Second, a marketing statement has been removed from the labeling which stated "kills adult fleas before they lay eggs," as this was requested by EPA to be removed from the list of optional marketing claims. The statements have been identified in the highlighted version of the old label, and new label reflects the removal of this statement.

If you have any questions or comments, please feel free to contact me at your earliest convenience. If I cannot be reached, please contact Cory Herr, Director of U.S. Regulatory Innovation, at (317) 651-2776 or at herr_cory_t@elanco.com.

Sincerely,

Aaron Johnson, DVM, MS
Principal Regulatory Consultant
Elanco Animal Health
Office: 317-276-4021
Fax: 317-277-4167
Email: ajohnson@elanco.com





Elanco Animal Health

2500 Innovation Way
Greenfield, IN 46140
317.276.2000

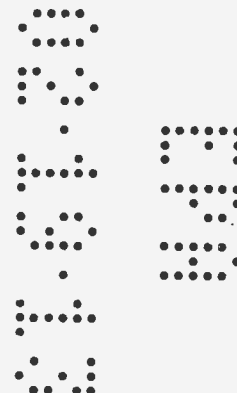
RE: Notification of Primary Brand Change [EPA Registration # 72642-10]

Explanation Continued:

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under section 12 and 14 of FIFRA."

Signature  Date 12 Feb 2013
Aaron E. Johnson

Aaron E. Johnson, DVM, MS
Elanco Animal Health
Principal Consultant, Regulatory Affairs
(317) 276-0421
(317) 277-4167 (fax)
ajohnson@elanco.com



Marketing claims: see lists at the end of the draft labels.
Alternative language in (parentheses)

NOTIFICATION

MAY 06 2013

CARTON LABEL

FRONT PANEL

Cheristin™ for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.

Picture of Cat or Kitten

ACTIVE INGREDIENT

Spinetoram (CAS# 187166-40-1 & 187166-15-0) 11.2%

OTHER INGREDIENTS 88.8%
TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12 – 0.026 fl oz (0.77 ml) applicator

BACK PANEL

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

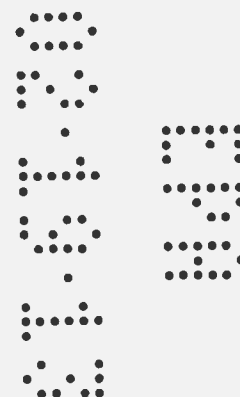
IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-10
EPA Est. No.



PACKAGE INSERT LABEL

Cheristin™ for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

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- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between the shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)



6. Discard empty applicator tube in the trash.

Picture/drawing
of opening the
tube.

Picture/drawing
of parting the
hair on neck at
base of head.

Picture/drawing
of applying the
product.

Monthly application is recommended to prevent and treat flea infestations. Cheristin™ for cats starts working in 30 minutes and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

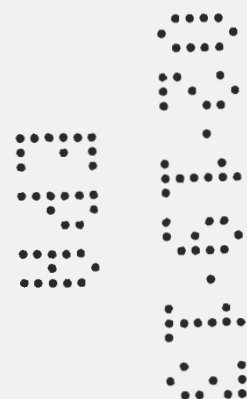
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY, WHATSOEVER, FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-10
EPA Est. No.



Applicator Labeling

Cheristin™ for cats
Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

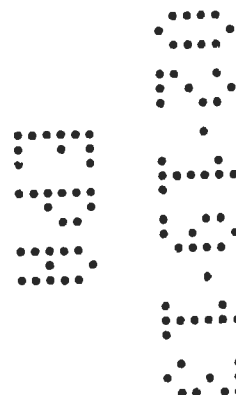
EPA Reg. No 72642-10

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.



Blister Labeling

Cheristin™ for cats
Spinetoram 11.2%

For Cats and Kittens 8 weeks of age (and older)

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-10

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

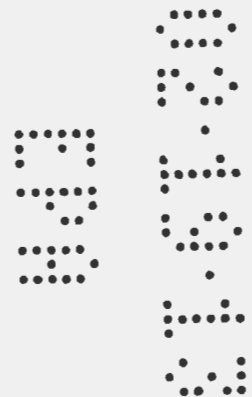
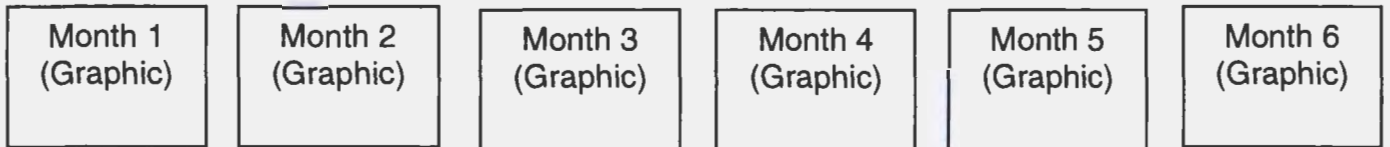


(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Cheristin™ for cats only to cats and kittens 8 weeks of age and older.

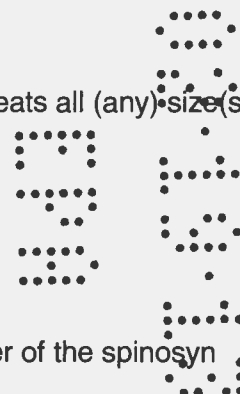
Visit www.CheristinForCats.com to sign up and receive an email reminder from your cat when it is time to receive Cheristin™ for cats.

Graphic of calendar



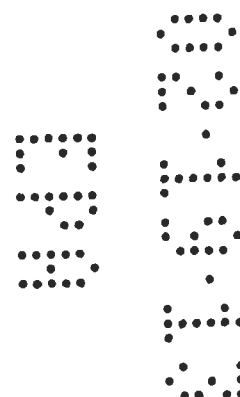
Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [*Ctenocephalides felis*] on cats (and kittens) 8 weeks of age or older only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective through 6 weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- Long-lasting flea control through 6 weeks
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Cheristin™ for cats, is a member of the spinosyn class of pesticide
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8



weeks of age (and older) only

- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control and prevention of fleas
- Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)



Marketing claims: see lists at the end of the draft labels.
Alternative language in (parentheses)

CARTON LABEL

FRONT PANEL

Cheristin™ for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.

Picture of Cat or Kitten

ACTIVE INGREDIENT

Spinetoram (CAS# 187166-40-1 & 187166-15-0) 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12 – 0.026 fl oz (0.77 ml) applicator

BACK PANEL**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Cheristin™ for cats starts working in 30 minutes and continues killing fleas for a full month after application.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION**

HAZARDS TO HUMANS

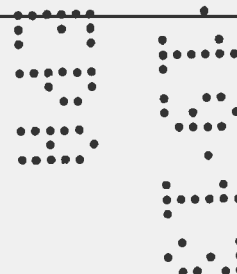
Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.



FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

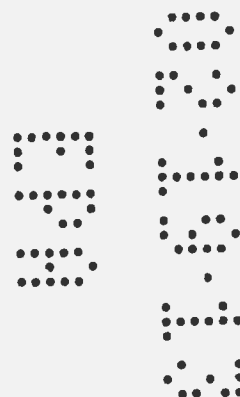
- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

Manufactured for

Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-10
EPA Est. No.



PACKAGE INSERT LABEL

Cheristin™ for cats

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read the entire label, directions for use and frequency of application each time before using the product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)
6. Discard empty applicator tube in the trash.

Picture/drawing
of opening the
tube.

Picture/drawing
of parting the
hair on neck at
base of head.

Picture/drawing
of applying the
product.

Monthly application is recommended to prevent and treat flea infestations. Cheristin™ for cats starts working in 30 minutes and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

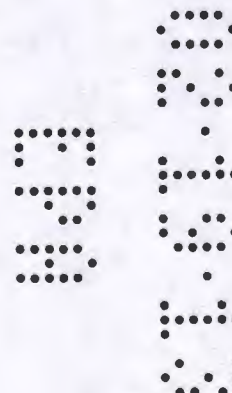
If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-10
EPA Est. No.



Applicator Labeling

Cheristin™ for cats
Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

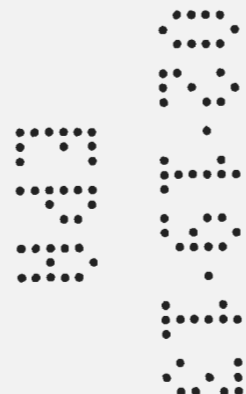
EPA Reg. No 72642-10

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.



Blister Labeling

Cheristin™ for cats
Spinetoram 11.2%

For Cats and Kittens 8 weeks of age (and older)

0.026 fl oz (0.77 mL)

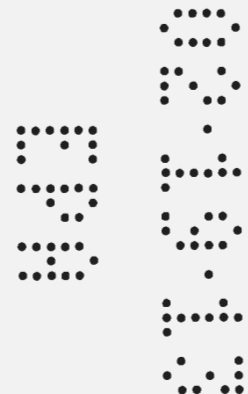
EPA Reg. No 72642-10

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

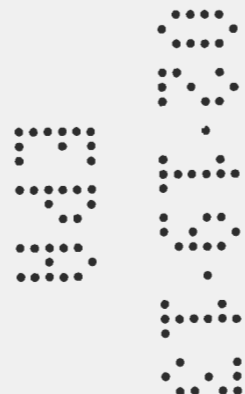
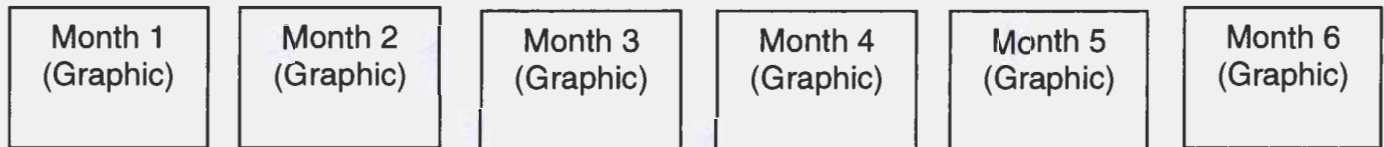


(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Cheristin™ for cats only to cats and kittens 8 weeks of age and older.

Visit www.CheristinForCats.com to sign up and receive an email reminder from your cat when it is time to receive Cheristin™ for cats.

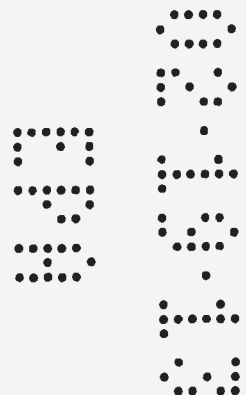
Graphic of calendar



Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [*Ctenocephalides felis*] on cats (and kittens) 8 weeks of age or older only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective through 6 weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- Long-lasting flea control through 6 weeks
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Cheristin™ for cats, is a member of the spinosyn class of pesticide
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8 weeks of age (and older) only
- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control

- and prevention of fleas
- Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)



(label to be placed near discharge control valve, this statement can be removed from printed label)

Cheristin™ for cats

spinetoram

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.20%

OTHER INGREDIENTS 88.80%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for the further manufacture or repacking of a registered pesticide product for companion animals.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in original package only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

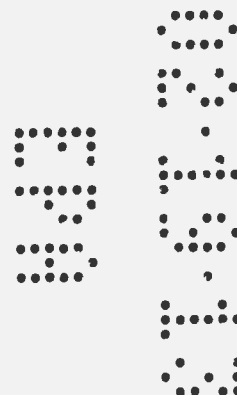
Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Never pour unused product down the drain or on the ground.

Container Handling: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into manufacturing process or appropriate waste collection system. Fill the container about 10% full with water, and if possible, spray all sides while adding water. If practical, agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into a waste collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-10
EPA Est. No. 70996-CAN-002

NET CONTENTS: _____
(may be completed by manual entry)



Decision Information for 72642

Decision Seq: **475624** Action Code: **332,NOTIFICATION,,30**

FFS Start Date: Tentative Ind: **No** **Start/Stop Clock** FGPA Clock:

Due Date: **21-Mar-2013** 75-Day Due Date: Days Elapsed:

OPP Target Due Date: 21-Day Due Date: FFS Original Decision:

Negotiated Due Date: 45/90 Due Date:

Registrant: Predecisional Due Date:

Response Due Date:

Current Status: **PENDING (26-Feb-2013)**

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

75 Day Letters **45/90 Day Screen** **Primary Decisions**

FFS Negotiated Due Dates **OPP Target Due Date** **Decision Comments** **Payment** **Unmatched Payments**

Decision Ownership **Receipts** **Data Package** **Reduced Risk** **Meetings & Milestones** **FFS Information**

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 931163	Suzanne Mark Mark Hullester	72642-10	21-Mar-2013	PENDING

notification primary brand name

Viewing Record 1 of 1

Samantha
Please complete by 5/14.

Thanks, Mark

Receipt for Section 3

S: Resubmission: ☐ Yes ☒ No

Regulatory Type: Fee For Service: ☐ Yes ☒ No

Application Type:

Company:

Risk Manager:

Product #: Product Name:

Override#:

Me Too Section3: Me Too Product Name:

Application Date: OPP Rec'd Date:

Front End Date: Risk Manager Send Date:

FFS Due Date: Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Form A: ☐ Signature Date: Form B: ☐ Signature Date:

Receipt Content	Des
Paper Label	



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

72642-10

Date of Issuance:

JAN 17 2013

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Spinetoram 11.2% Cats

Name and Address of Registrant (include ZIP Code):

Elanco Animal Health, A Division of Eli Lilly & Company
2500 innovation Way
P.O. Box 708
Greenfield, IN 46140

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered//reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with section 3(c)(7)(A) of FIFRA provided that you:

1. Submit and/or cite all data required for registration of your product under section 3(c)(5) of FIFRA when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under section 4 of FIFRA.
2. Submit within 12 months of the date of issuance of this Registration Notice, acceptable guideline studies for Storage Stability study (OPPTS GLN: 830.6317) and Corrosion Characteristics study (OPTS GLN: 830.6320) for this product.
3. Change the product registration number to "EPA Reg. No. 72642-10"
(continued on page 2)

Signature of Approving Official:

See page 2

Mark Suarez, Product Manager (13)
Insecticide Branch, Registration Division (7504P)

Date:

JAN 17 2013

EPA Form 8570-6

Conditions of acceptance

1. This registration is now time-limited and expires two years from the date of this letter.
2. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning April 1, 2013.

The quarterly reports are due two months after the quarter ends. Please flag any Confidential Business Information as such. Enhanced incident reporting should be submitted to the Product Manager. Quarterly sales information should be submitted to the Registration Division, Immediate Office (attn: Kaitlon Keller).

The following is a list of information that must be included in the quarterly reports for each incident:

EPA Registration Number
Product name (brand name)
Lot #

Where purchased: internet, store, veterinarian
Active Ingredient(s)
Weight range for product

Date on which incident occurred. (mm/dd/yyyy)
State in which the incident occurred. (standard 2 letter abbreviation)
Registrant case #

Species: dog, cat, other (specify)
Breed: (as reported by pet owner)
Age: months or years
Sex: M, F, or neutered
Weight: pounds

Primary Route of Exposure: dermal, oral, other animal, inhalation, other
Body System: neurological, dermatological, GI, respiratory, ocular, other
Major signs noted with separate column for each sign, using standard terminology
Time to Onset: (hours, days)
Treated by veterinarian: yes or no
First time product used: yes or no
Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
Any known precondition
EPA Severity Code: death, major, moderate, minor
Outcome: died, recovered, still treated, unknown

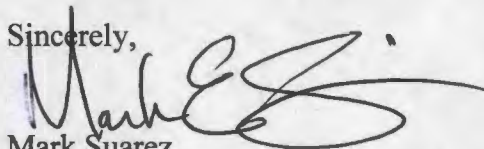
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

- All incidents should be reported including all minor dermal and ocular irritation reports.
- Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.
- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.
- Table showing number of incidents for each dog breed.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.

Report aggregate incidents, but do not combine moderate and minor incidents.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. If EPA determines that future mitigation measures are necessary for all spot-on products, the Agency will inform registrants and if needed, EPA may take regulatory action. If you have any questions contact Driss Benmhend at 703-308-9525 or by e-mail at: Benmhend.driss@epa.gov.

Sincerely,



Mark Suarez
Product Manager 13,
Insecticide Branch
Registration Division (7504P)

Enclosure: Label Stamped "with Comments"

(label to be placed near discharge control valve, this statement can be removed from printed label)

Spinetoram 11.2% Cat

spinetoram

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.20%

OTHER INGREDIENTS 88.80%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED
with COMMENTS
In EPA Letter Dated
JAN 17 2013
Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.
72642-10

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for the further manufacture or repacking of a registered pesticide product for companion animals.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in original package only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Never pour unused product down the drain or on the ground.

Container Handling: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into manufacturing process or appropriate waste collection system. Fill the container about 10% full with water, and if possible, spray all sides while adding water. If practical, agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into a waste collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No. 70996-CAN-002

NET CONTENTS: _____
(may be completed by manual entry)

Marketing claims: see lists at the end of the draft labels.
Alternative language in (parentheses)

CARTON LABEL

FRONT PANEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.

Picture of Cat or Kitten

ACTIVE INGREDIENT

Spinetoram (CAS# 187166-40-1 & 187166-15-0) 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12 – 0.026 fl oz (0.77 ml) applicator

BACK PANEL

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No.

PACKAGE INSERT LABEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between the shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)

6. Discard empty applicator tube in the trash.

Picture/drawing
of opening the
tube.

Picture/drawing
of parting the
hair on neck at
base of head.

Picture/drawing
of applying the
product.

Monthly application is recommended to prevent and treat flea infestations. Spinetoram 11.2% Cat starts working in 30 minutes, kills adult fleas before they lay eggs and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No.

Applicator Labeling

Spinetoram 11.2% Cat
Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

Spinetoram 11.2% Cat
Spinetoram 11.2%

For Cats and Kittens 8 weeks of age (and older)

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

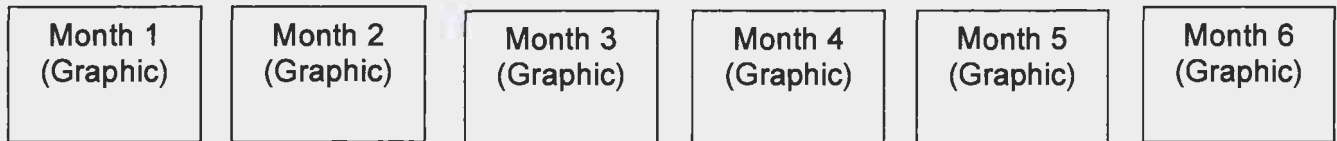
Lot No.

(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Spinetoram 11.2% Cat for cats and kittens 8 weeks of age and older.

Visit www.elanco.com to sign up and receive an email reminder from your cat when it is time to receive Spinetoram 11.2% Cat.

Graphic of calendar



Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [*Ctenocephalides felis*] on cats (and kittens) 8 weeks of age or older only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective through 6 weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- Long-lasting flea control through 6 weeks
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Spinetoram 11.2% Cat, is a member of the spinosyn class of pesticide
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8

- weeks of age (and older) only
- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control and prevention of fleas
- Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)

Marketing claims: see lists at the end of the draft labels.
Alternative language in (parentheses)

CARTON LABEL

FRONT PANEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.

Picture of Cat or Kitten

ACTIVE INGREDIENT

Spinetoram (CAS# 187166-40-1 & 187166-15-0) 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12 – 0.026 fl oz (0.77 ml) applicator

BACK PANEL

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Spinetoram 11.2% Cat starts working in 30 minutes, kills adult fleas before they lay eggs and continues killing fleas for a full month after application.

**PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION**

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

Manufactured for

Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No.

PACKAGE INSERT LABEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age or weighing less than 1.8 lb. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
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- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read the entire label, directions for use and frequency of application each time before using the product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)
6. Discard empty applicator tube in the trash.

Picture/drawing
of opening the
tube.

Picture/drawing
of parting the
hair on neck at
base of head.

Picture/drawing
of applying the
product.

Monthly application is recommended to prevent and treat flea infestations. Spinetoram 11.2% Cat starts working in 30 minutes, kills adult fleas before they lay eggs and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No.

Applicator Labeling

Spinetoram 11.2% Cat
Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

Spinetoram 11.2% Cat
Spinetoram 11.2%

For Cats and Kittens 8 weeks of age (and older)

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

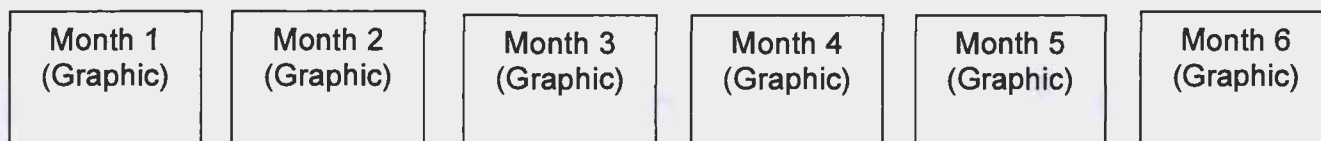
Lot No.

(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Spinetoram 11.2% Cat for cats and kittens 8 weeks of age and older.

Visit www.elanco.com to sign up and receive an email reminder from your cat when it is time to receive Spinetoram 11.2% Cat.

Graphic of calendar



Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [*Ctenocephalides felis*] on cats (and kittens) 8 weeks of age or older only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective through 6 weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- Long-lasting flea control through 6 weeks
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)
- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Spinetoram 11.2% Cat, is a member of the spinosyn class of pesticide
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8 weeks of age (and older) only
- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control

- and prevention of fleas
- Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)

(label to be placed near discharge control valve, this statement can be removed from printed label)

Spinetoram 11.2% Cat

spinetoram

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.20%

OTHER INGREDIENTS 88.80%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID

IF IN EYES:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for the further manufacture or repacking of a registered pesticide product for companion animals.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in original package only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Never pour unused product down the drain or on the ground.

Container Handling: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into manufacturing process or appropriate waste collection system. Fill the container about 10% full with water, and if possible, spray all sides while adding water. If practical, agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into a waste collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No. 70996-CAN-002

NET CONTENTS: _____
(may be completed by manual entry)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

From: Kevin Sweeney, Senior Entomologist

A handwritten signature in black ink, appearing to read "Kevin Sweeney", with a long, sweeping checkmark-like stroke extending from the end.

Date: January 10, 2013

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 404873

Decision no.: 466770

Submission no: 919462

Action code: R310

Product Name: Spinetoram 11.2% Cat

EPA Reg. No or File Symbol: 72642-RN

Formulation Type: RTU pet spot-on

Ingredients statement from the label with PC codes included: 11.2 % spinetoram (PC codes: 11009 & 11008)

Use pattern: Topical cat spot-on for cats weighing more than 1.8 lbs.

Application rates of product/active ingredient: One tube per cat (0.026 fl oz/0.77ml).

(Efficacy testing was done with 0.70 ml dose)

OCSP Guideline: 810.3300

I. Action Requested: Review label and submitted efficacy data.

II. Background: The registrant submitted a new cat spot-on product that they claim is substantially similar to EPA Reg. No. 72642-9. The product specific efficacy data were submitted for fleas only as that is the only pest on the proposed label.

III. Study Reviews:

Please find the primary reviews attached. I have summarized the review results below.

MRID48875806. Everett, W.R. 2012. Efficacy of Spinetoram 11.2% (w/w) Topical Formulation against Cat Fleas on Adult Cats.

Conclusion: The study is acceptable. The study demonstrated that the product controlled cat fleas for up to 37 days post-treatment. The product was effective based on counts at days 2, 9, 16, 23, 30 and 37. Results were expressed in terms of geometric and arithmetic means. Treated animals were compared to control treated with a vehicle control solution.

MRID48875807. Young, D.R. 2012. Efficacy of Spinetoram 11.2% (w/w) Topical Formulation against Cat Fleas on Adult Cats.

Conclusion: The study is acceptable. The study demonstrated that the product controlled cat fleas for up to 37 days post-treatment. The product was effective based on counts at days 2, 9, 16, 23, 30 and 37. Results were expressed in terms of geometric and arithmetic means. Treated animals were compared to control treated with a vehicle control solution.

MRID48875808. Everett, W.R. 2012. Knockdown and Speed of Kill Effectiveness of Spinetoram 11.2% (w/w) Topical Formulation Administered to Cats for the Treatment of Cat Fleas and its Residual Efficacy (Interim Report).

Conclusion: The study is acceptable. The primary review does not mention it, but there were two minor deviations reported in the study. These deviations did not have significant impacts on the study outcomes. The data support speed of kill claims: 8 hours or greater; and starts killing within 30 minutes.

IV. Entomologist's Recommendations:

1. The submitted data demonstrate control of fleas for up to 37 days with one spot-on application. The claim "continues killing fleas for a full month after application" is supported.
2. The submitted data show that following application, the product starts working within 30 minutes and kills fleas by 8 hours post-treatment or within 8 hours of exposure to the treatment
3. The data do not show that "Spinetoram 11.2% Cat..., "Kills adult fleas before the(y) lay eggs." This claim should be removed. "Kills fleas before they lay eggs"
4. I did not review the website referred to on the label.
5. Additional marketing claims:
 - Remove any claims greater than 6 weeks. Only one study showed activity greater than

37 days. The other studies showed up to 37 days of control.

- The four bulleted claims referring to: mode of action; lack of interaction with other pesticides; ...activation of motor neurons; and hyper-excitation resulting in prostration and paralysis of fleas; were not evaluated in these studies. I default to the risk manager and/or PM to determine if these claims are true and appropriate for consumer product labeling.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 488758-06. W.R. Everett. Application to Register Spinetoram 11.2% Cat: A Once Monthly Topical for the Prevention and Treatment of Flea Infestation on Cats and Kittens, Eight Weeks and Older. June 11, 2012.

OCSPP 810.3300 (Treatments to Control Pests of Humans and Pets)

Product Name: Spinetoram 11.2% Cat
EPA Reg. No. or File Symbol: 72642-RN
Decision number: 466770
DP number: 404873

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summittec Corporation
Task Order No.: 2-90

Primary Reviewer:
Robert H. Ross, M.S.

Signature: Robert H. Ross
Date: DEC 27 2012

Secondary Reviewers:
Gene Burgess, Ph.D.

Signature: Gene Burgess ^{AE}
Date: DEC 27 2012

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross
Date: DEC 27 2012

Quality Assurance:
Angie Edmonds, B.S.

Signature: Angie Edmonds
Date: DEC 27 2012

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

Summittec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE: OCSSP 810.3300 (Treatments to Control Pests of Humans and Pets)
MRID:	488758-06. W.R. Everett. Application to Register Spinetoram 11.2% Cat: A Once Monthly Topical for the Prevention and Treatment of Flea Infestation on Cats and Kittens, Eight Weeks and Older. June 11, 2012.
DP BARCODE:	404873
DECISION NO:	466770
SUBMISSION NO:	919462
SPONSOR:	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140
TESTING FACILITY:	Bertek, Inc. 104 Wilson Bottoms Road Greenbier, AR 72058
STUDY DIRECTOR:	William R. Everett, Ph.D.
SUBMITTER:	Katherine A. Meyer Elanco Animal Health
STUDY COMPLETED:	11/06/2012

**CONFIDENTIALITY
CLAIMS:**

None

**GOOD LABORATORY
PRACTICE:**

The following is a detailed description of all differences between the practices used in the study and those required by 40 CFR 160:

1. The commercial animal ration used in the study was not analyzed for specific contaminants because none were expected.
2. The drinking water used in the study was not analyzed for specific contaminants because none were expected. This was potable water obtained from the local public water supply. The water is routinely analyzed by the local water authority for suitability as drinking water.
3. The method used to assay the GLP vehicle control (EAH-FEB-12-P01) and test substance (EAH-FEB-12-003) lots was not fully validated before study initiation. On 14 February 2012, the GLP method validation (Study No. 68306, Method Validation for the Quantitation of 11.2% w/wt Spinetoram J and L in Formulation) was initiated and the lab phase was completed on 30 April 2012. Furthermore, ABC Lab QAU completed the raw data review of the method validation on 15 May 2012. The method validation was in progress when the material was originally assayed and after the completion of the QAU review the GLP CoA's were issued for both lots EAH-FEB-12-P01 and EAH-FEB-12-003. These two GLP lots were used to validate the method. The final assay results of lot EAH-FEB-12-003 after the method was validated did not change.
4. Data entry and statistical analysis of the data was performed by ClinData Services, Inc. who are compliant with GCP (Good Clinical Practices) and HIPAA standards. The data management software used is fully compliant with 21 CFR Part 11 standards for data integrity, confidentiality and security. The statistical analysis was performed using SAS software, which is recognized as an industry standard system. Although ClinData Services does not have a Quality Assurance unit to qualify the actual transformations performed, the quality review which was conducted for this study by ClinData Services personnel was per their local procedures.

TEST MATERIAL:

PRODUCT NAME: Spinetoram 11.2% Cat
EPA REGISTRATION NUMBER OR FILE SYMBOL:
72642-RN
ACTIVE INGREDIENT NAME: Spinetoram
CHEMICAL NAME: Not given
A.I. %: 11.2%
PC CODES: 110008 and 110009
CAS NO.: 187166-40-1 and 187166-15-0
FORMULATION TYPE: Spot on
PRODUCT APPLICATION RATE(S) : One tube (0.026 fl
oz; 0.77 ml)
ACTIVE INGREDIENT APPLICATION RATE(S): Not
given

**PROPOSED LABEL
MARKETING CLAIMS:**

Kills fleas within 8 hours. Starts killing fleas in 30
minutes. One treatment prevents further flea infestations
for up to 7 weeks.

STUDY REVIEW

Purpose: To confirm the effectiveness of 0.7 ml 11.2% in cats experimentally infested with adult cat fleas.

MATERIALS AND METHODS

Test Location: In laboratory of Bertek, Inc., Greenbier, AR

Test Material(s): Spinetoram 11.2%, 0.70 ml – same as product label except test material volume was 0.07 ml less than label amount of 0.77 ml

Test Species Name, Life Stage, Sex and Age: Adult cat flea (*Ctenocephalides felis*)

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Table 1 provides details on experimental animals and Table 2 gives the schedule of events. Cats were housed individually in cages and treated cats were not housed directly over control cats. Treatments were administered once topically at the base of the skull after parting each animal's hair. The inclusion criteria were as follows:

- Cats were able to maintain at least 30 % of the experimental flea infestations applied during the pre-treatment period for ranking and allocation.
- Cats had a hair coat and disposition that allowed for complete and thorough combing to remove all fleas during the comb counting procedure.
- Cats were in good health.

Table 1. Animal Demographics

Parameter		Spinetoram	Vehicle Control	p-value*
Animal Source+	Site Colony	8 (100.0%)	8 (100.0%)	
Breed Category+	Crossbred	8 (100.0%)	8 (100.0%)	
Age (months)++	N	7	6	0.2097
	Mean (SD)	17.00 (8.21)	12.50 (0.55)	
	Median	12.00	12.50	
	Min, Max	12.00, 29.00	12.00, 13.00	
Gender	Female Intact	5 (62.5%)	5 (62.5%)	1.0000
	Male Intact	3 (37.5%)	2 (25.0%)	
	Male Neutered	0 (0.0%)	1 (12.5%)	
Hair Length	Short	8 (100.0%)	7 (87.5%)	1.0000
	Medium	0 (0.0%)	1 (12.5%)	
Completed Study		8 (100.0%)	8 (100.0%)	1.0000

* P-values for categorical variables derived by Fisher's Exact (2-tail) test.

† P-values for continuous variables derived by analysis of variance with treatment as factor

+ NOTE: P-values for Animal Source and Breed Category were not calculated as all animals were obtained from the same source and same breed category.

++ NOTE: Age was unknown for three animals (one in the Spinetoram group and two in the Vehicle Control group).

Table 2. Schedule of Events

Study Day	Activities
-14	Receipt and/or identification of animals suitable for inclusion in study. Begin once daily general health observations of all cats.
-12	Bathe and groom cats. Conduct physical exams.
-7	Infest at least 20 cats with approximately 100 fleas.
-5	Comb count 48 hours after infestation. Weigh cats.
-4	Allocate 16 cats to treatment groups.
-1	Infest cats in both treatment groups with approximately 100 fleas.
0 (am)	Administer treatments in the morning Post treatment Observations
1-37	Twice daily general health observations.
1-7	Aesthetic Observations
2	Flea comb count
7	Flea Infest
9	Flea comb count
14	Flea Infest
16	Flea comb count
21	Flea Infest
23	Flea comb count
28	Flea Infest
30	Flea comb count
35	Flea Infest
37	Flea comb count

List the treatments including untreated control :

Treatment Group	Dose Rate	Study Days for Flea Infestations and Comb Counts	
		Infestations (Day)	Comb Counts
1	0.7 ml of Spinetoram 11.2% (wt/wt) Topical Formulation applied on Study Day 0	-1, 7, 14, 21, 28 and 35	Approximately 48 hours after treatment (Study Day 2) or infestation (Study Days 9, 16, 23, 30 and 37)
2	0.7 ml of Vehicle Control	-1, 7, 14, 21, 28 and 35	Approximately 48 hours after treatment (Study Day 2) or infestation (Study Days 9, 16, 23, 30 and 37)

Number of replicates per treatment: 8

Number of individuals per replicate: 1

Length of exposure to treatment (time in seconds, minutes or hours): 37 days

Were tested specimens transferred to clean containers? NA

Experimental conditions (state relative humidity, temperature, and photoperiod): Laboratory conditions with a 12:12 light:dark cycle

Data or endpoints collected/recorded: Live fleas counts on days 2, 9, 16, 23, 30, and 37

Data analysis: Geometric and arithmetic mean live flea counts

RESULTS

As shown in Tables 3 and 4, the test product was very effective.

Table 3. Geometric Mean Live Flea Counts and Calculated Percent Efficacy

Count Day	Vehicle Control	Spinetoram Treated	% Efficacy
Day 2	86.41	0.00	100.00
Day 9	74.47	0.00	100.00
Day 16	76.35	0.00	100.00
Day 23	77.21	0.49	99.37
Day 30	56.34	0.09	99.84
Day 37	59.34	1.28	97.85

Table 4. Arithmetic Mean Live Flea Counts and Calculated Percent Efficacy

Count Day	Vehicle Control	Spinetoram Treated	% Efficacy
Day 2	87.00	0.00	100.00
Day 9	76.38	0.00	100.00
Day 16	77.63	0.00	100.00
Day 23	78.00	0.75	99.04
Day 30	59.88	0.13	99.79
Day 37	61.25	2.00	96.73

Study Author's Conclusions

Excellent control of cat fleas for at least 37 days.

Reviewer's Conclusions

The test material gave excellent results for up to 37 days. Control data were acceptable. No deviations from protocol were noted. Results for individual cats were not provided.

Reviewer's Recommendations

The study is acceptable and supports the label claim of one treatment prevents further flea infestations for up to 7 weeks. It was not intended to support the claim of fast action which is supported by results in MRID 48875808.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 488758-07. D.R. Young. Application to Register Spinetoram 11.2% Cat: A Once Monthly Topical for the Prevention and Treatment of Flea Infestation on Cats and Kittens, Eight Weeks and Older. June 11, 2012.

OCSSP 810.3300 (Treatments to Control Pests of Humans and Pets)

Product Name: Spinetoram 11.2% Cat
EPA Reg. No. or File Symbol: 72642-RN
Decision number: 466770
DP number: 404873

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-90

Primary Reviewer:
Robert H. Ross, M.S.

Signature: Robert H. Ross
Date: _____

Secondary Reviewers:
Gene Burgess, Ph.D.

Signature: Gene Burgess ^{AE}
Date: DEC 27 2012

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross
Date: DEC 27 2012

Quality Assurance:
Angie Edmonds, B.S.

Signature: Angie Edmonds
Date: DEC 27 2012

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Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE: OCSSP 810.3300 (Treatments to Control Pests of Humans and Pets)
MRID:	488758-07. D.R. Young. Application to Register Spinetoram 11.2% Cat: A Once Monthly Topical for the Prevention and Treatment of Flea Infestation on Cats and Kittens, Eight Weeks and Older. June 11, 2012.
DP BARCODE:	404873
DECISION NO:	466770
SUBMISSION NO:	919462
SPONSOR:	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140
TESTING FACILITY:	Young Veterinary Research Services 213 South Roselawn Avenue Turlock, CA 95380-9124
STUDY DIRECTOR:	David R. Young, D.V.M., Ph.D.
SUBMITTER:	Katherine A. Meyer Elanco Animal Health
STUDY COMPLETED:	11/06/2012

**CONFIDENTIALITY
CLAIMS:**

None

**GOOD LABORATORY
PRACTICE:**

The following is a detailed description of all differences between the practices used in the study and those required by 40 CFR 160:

- 1 The method used to assay the GLP vehicle control (EAH-FEB-12-P01) and test substance (EAH-FEB-12-003) lots was not fully validated before study initiation. On 14 February 2012, the GLP method validation (Study No. 68306, Method Validation for the Quantitation of 11.2% wt/wt Spinetoram I and L in Formulation) was initiated and the lab phase was completed on 30 April 2012. Furthermore, ABC Lab QAU completed the raw data review of the method validation on 15 May 2012. The method validation was in progress when the material was originally assayed and after the completion of the QAU review the GLP CoA's were issued for both lots EAH-FEB-12-P01 and EAH-FEB-12-003. These two GLP lots were used to validate the method. The final assay result of lot EAH-FEB-12-003 after the method was validated did not change.
- 2 Data entry and statistical analysis of the data was performed by ClinData Services, Inc. who are compliant with GCP (Good Clinical Practices) and HIPAA standards. The data management software used is fully compliant with 21 CFR Part 11 standards for data integrity, confidentiality and security. The statistical analysis was performed using SAS software, which is recognized as an industry standard system. Although ClinData Services does not have a Quality Assurance unit to qualify the actual transformations performed, the quality review which was conducted for this study by ClinData Services personnel was per their local procedures.
- 3 The commercial feline ration and the drinking water used in the study were not analyzed under GLP standards.

These exceptions would not be expected to adversely impact the conduct of the study.

TEST MATERIAL:

PRODUCT NAME: Spinetoram 11.2% Cat
EPA REGISTRATION NUMBER OR FILE SYMBOL:
72642-RN
ACTIVE INGREDIENT NAME: Spinetoram
CHEMICAL NAME: Not given
A.I. %: 11.2%
PC CODEs: 110008 and 110009
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for up to 7 weeks.

STUDY REVIEW

Purpose: To confirm the effectiveness of 0.7 ml 11.2% in cats experimentally infested with adult cat fleas.

MATERIALS AND METHODS

Test Location: In laboratory of Bertek, Inc., Greenbier, AR

Test Material(s): Spinetoram 11.2%, 0.70 ml – same as product label except test material volume was 0.07 ml less than label amount of 0.77 ml

Test Species Name, Life Stage, Sex and Age: Adult cat flea (*Ctenocephalides felis*)

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Table 1 provides details on experimental animals and Table 2 gives the schedule of events. Cats were housed individually in cages and treated cats were not housed directly over control cats. Treatments were administered once topically at the base of the skull after parting each animal's hair. The inclusion criteria were as follows:

- Cats were able to maintain at least 30 % of the experimental flea infestations applied during the pre-treatment period for ranking and allocation.
- Cats had a hair coat and disposition that allowed for complete and thorough combing to remove all fleas during the comb counting procedure.
- Cats were in good health.

Table 1. Animal Demographics

Parameter		Spinetoram	Vehicle Control	p-value*
Animal Source†	Site Colony	8 (100.0%)	8 (100.0%)	
Breed Category†	Crossbred	8 (100.0%)	8 (100.0%)	
Approx. Age (months)	N	8	8	0.4106
	Mean (SD)	103.13 (38.38)	85.50 (44.50)	
	Median	101.50	70.00	
	Min, Max	58.00, 184.00	36.00, 160.00	
Gender	Female Intact	4 (50.0%)	3 (37.5%)	0.8042
	Female Spayed	2 (25.0%)	1 (12.5%)	
	Male Intact	1 (12.5%)	3 (37.5%)	
	Male Neutered	1 (12.5%)	1 (12.5%)	
Hair Length	Short	6 (75.0%)	6 (75.0%)	1.0000
	Long	2 (25.0%)	2 (25.0%)	
Completed Study		8 (100.0%)	8 (100.0%)	1.0000

* P-values for categorical variables derived by Fisher's Exact (2-tail) test.

P-values for continuous variables derived by analysis of variance with treatment as factor

† NOTE: P-values for Animal Source and Breed Category were not calculated as all animals were obtained from the same source and same breed category

Table 2. Schedule of Events

Schedule of Events	
Study Day	Activities
-14 to -10	Receipt and/or identification of animals suitable for inclusion in study. Begin daily general health observations of all cats. Bathe and groom cats. Conduct physical exams.
-9	Infest at least 20 cats with approximately 100 fleas.
-7 to -3	Comb count 48 hours after infestation. Weigh cats. Allocate 16 cats to treatment groups.
-1	Infest cats in both treatment groups with approximately 100 fleas.
0 (am)	Administer treatments in the morning Post treatment Observations
1-7	Aesthetic Observations
2	Flea comb count
7	Flea Infest
9	Flea comb count
14	Flea Infest
16	Flea comb count
21	Flea Infest
23	Flea comb count
28	Flea Infest
30	Flea comb count
35	Flea Infest
37	Flea comb count

List the treatments including untreated control :

Treatment Group	Dose Rate	Study Days for Flea Infestations and Comb Counts	
		Infestations (Day)	Comb Counts
1	0.7 ml of Spinetoram 11.2% (wt/wt) Topical Formulation applied on Study Day 0	-1, 7, 14, 21, 28 and 35	Approximately 48 hours after treatment (Study Day 2) or infestation (Study Days 9, 16, 23, 30 and 37)
2	0.7 ml of Vehicle Control	-1, 7, 14, 21, 28 and 35	Approximately 48 hours after treatment (Study Day 2) or infestation (Study Days 9, 16, 23, 30 and 37)

Number of replicates per treatment: 8

Number of individuals per replicate: 1

Length of exposure to treatment (time in seconds, minutes or hours): 37 days

Were tested specimens transferred to clean containers? NA

Experimental conditions (state relative humidity, temperature, and photoperiod): Laboratory conditions with a 12:12 light:dark cycle

Data or endpoints collected/recorded: Live fleas counts on days 2, 9, 16, 23, 30, and 37

Data analysis: Geometric and arithmetic mean live flea counts

RESULTS

As shown in Tables 3 and 4, the test product was very effective.

Table 3. Geometric Mean Live Flea Counts and Calculated Percent Efficacy

Count Day	Vehicle Control	Spinetoram Treated	% Efficacy
Day 2	56.06	0.00	100.00
Day 9	65.46	0.00	100.00
Day 16	64.69	0.00	100.00
Day 23	58.10	0.19	99.67
Day 30	71.18	1.39	98.05
Day 37	67.35	2.68	96.01

Table 4. Arithmetic Mean Live Flea Counts and Calculated Percent Efficacy

Count Day	Vehicle Control	Spinetoram Treated	% Efficacy
Day 2	57.00	0.00	100.00
Day 9	67.13	0.00	100.00
Day 16	65.63	0.00	100.00
Day 23	61.00	0.38	99.39
Day 30	73.38	2.13	97.10
Day 37	68.25	7.13	89.56

Study Author's Conclusions

Excellent control of cat fleas for at least 37 days.

Reviewer's Conclusions

The test material gave excellent results for up to 37 days. Control data were acceptable. No deviations from protocol were noted. Results for individual cats were not provided.

Reviewer's Recommendations

The study is acceptable and supports the label claim of one treatment prevents further flea infestations for up to 7 weeks. It was not intended to support the claim of fast action which is supported by results in MRID 48875808.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 488758-08. W.R. Everett. Application to Register Spinetoram 11.2% Cat: A Once Monthly Topical for the Prevention and Treatment of Flea Infestation on Cats and Kittens, Eight Weeks and Older. June 19, 2012.

OCSSP 810.3300 (Treatments to Control Pests of Humans and Pets)

Product Name: Spinetoram 11.2% Cat
EPA Reg. No. or File Symbol: 72642-RN
Decision number: 466770
DP number: 404873

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summittec Corporation
Task Order No.: 2-90

Primary Reviewer:
Robert H. Ross, M.S.

Signature: Robert H. Ross
Date: DEC 27 2012

Secondary Reviewers:
Gene Burgess, Ph.D.

Signature: Gene Burgess ^{AE}
Date: DEC 27 2012

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross
Date: DEC 27 2012

Quality Assurance:
Angie Edmonds, B.S.

Signature: Angie Edmonds
Date: DEC 27 2012

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

Summittec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE: OCSSP 810.3300 (Treatments to Control Pests of Humans and Pets)
MRID:	MRID 488758-08. W.R. Everett. Application to Register Spinetoram 11.2% Cat: A Once Monthly Topical for the Prevention and Treatment of Flea Infestation on Cats and Kittens, Eight Weeks and Older. June 19, 2012.
DP BARCODE:	404873
DECISION NO:	466770
SUBMISSION NO:	919462
SPONSOR:	Elanco Animal Health 2500 Innovation Way Greenfield, IN 46140
TESTING FACILITY:	Bertek, Inc. 104 Wilson Bottoms Road Greenbier, AR 72058
STUDY DIRECTOR:	William R. Everett, Ph.D.
SUBMITTER:	Katherine A. Meyer Elanco Animal Health
STUDY COMPLETED:	19/06/2012

**CONFIDENTIALITY
CLAIMS:**

None

**GOOD LABORATORY
PRACTICE:**

The following is a detailed description of all differences between the practices used in the study and those required by 40 CFR 160:

1. The commercial animal ration used in the study was not analyzed for specific contaminants because none were expected.
2. The drinking water used in the study was not analyzed for specific contaminants because none were expected. This was potable water obtained from the local public water supply. The water is routinely analyzed by the local water authority for suitability as drinking water.
3. The method used to assay the GLP vehicle control (EAH-FEB-12-P01) and test substance (EAH-FEB-12-003) lots was not fully validated before study initiation. On 14 February 2012, the GLP method validation (Study No. 68306, Method Validation for the Quantitation of 11.2% wt/wt Spinetoram J and L in Formulation) was initiated and the lab phase was completed on 30 April 2012. Furthermore, ABC Lab QAU completed the raw data review of the method validation on 15 May 2012. The method validation was in progress when the material was originally assayed and after the completion of the QAU review the GLP CoA's were issued for both lots EAH-FEB-12-P01 and EAH-FEB-12-003. These two GLP lots were used to validate the method. The final assay result of lot EAH-FEB-12-003 after the method was validated did not change.

TEST MATERIAL:

PRODUCT NAME: Spinetoram 11.2% Cat
EPA REGISTRATION NUMBER OR FILE SYMBOL:
72642-RN
ACTIVE INGREDIENT NAME: Spinetoram
CHEMICAL NAME: Not given
A.I. %: 11.2%
PC CODEs: 110008 and 110009
CAS NO.: 187166-40-1 and 187166-15-0
FORMULATION TYPE: Spot on
PRODUCT APPLICATION RATE(S) : One tube (0.026 fl
oz; 0.77 ml)
ACTIVE INGREDIENT APPLICATION RATE(S): Not
given

**PROPOSED LABEL
MARKETING CLAIMS:**

Kills fleas within 8 hours. Starts killing fleas in 30
minutes. One treatment prevents further flea infestations
for up to 7 weeks.

STUDY REVIEW

Purpose: To confirm the speed of kill and effectiveness of 0.7 ml 11.2% in cats experimentally infested with adult cat fleas up to 44 days post treatment.

MATERIALS AND METHODS

Test Location: In laboratory of Bertek, Inc., Greenbier, AR

Test Material(s): Spinetoram 11.2%, 0.70 ml – same as product label except test material volume was 0.07 ml less than label amount of 0.77 ml

Test Species Name, Life Stage, Sex and Age: Adult cat flea (*Ctenocephalides felis*)

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Male and female mixed breed short hair cats weighing 4.8 to 13.1 lbs and who were > 7 months as of Day 0 were used. Table 1 gives the schedule of events. Cats were housed individually in cages and treated cats were not housed directly over control cats. Treatments were administered once topically at the base of the skull after parting each animal's hair. The inclusion criteria were as follows:

- Cats were able to maintain at least 30 % of the experimental flea infestations applied during the pre-treatment period for ranking and allocation.
- Cats had a hair coat and disposition that allowed for complete and thorough combing to remove all fleas during the comb counting procedure.
- Cats were in good health.

Table 1. Schedule of Events

Schedule of Events	
Study Day	Activities
-14	Receipt and/or identification of animals suitable for inclusion in study. Begin daily general health observations of all cats. Comb out and bathe each cat with non-insecticidal shampoo.
-13	Conduct physical exams.
-9	Infest 54 cats with approximately 100 fleas.
-7	Comb count 48 hours after infest. Weigh cats.
-6	Allocate 48 cats to treatment groups.
-1	Infest all cats with approximately 100 fleas.
0	Administer treatments (complete Treatment Dosing Record)
0 plus 0.5 hr.	Comb count cats in Treatment Groups 1 and 5.
0 plus 4 hr.	Comb count cats in Treatment Groups 2 and 6.
0 plus 8 hr.	Comb count cats in Treatment Groups 3 and 7.
0 plus 12 hr.	Comb count cats in Treatment Groups 4 and 8.
1-7	Aesthetic Observations
7	Infest cats in all treatment groups with approximately 100 fleas.
7 plus 0.5 hr.	Comb count cats in Treatment Groups 1 and 5.
7 plus 4 hr.	Comb count cats in Treatment Groups 2 and 6.
7 plus 8 hr.	Comb count cats in Treatment Groups 3 and 7.
7 plus 12 hr.	Comb count cats in Treatment Groups 4 and 8.
14	Infest cats in all treatment groups with approximately 100 fleas.
14 plus 0.5 hr.	Comb count cats in Treatment Groups 1 and 5.
14 plus 4 hr.	Comb count cats in Treatment Groups 2 and 6.
14 plus 8 hr.	Comb count cats in Treatment Groups 3 and 7.
14 plus 12 hr.	Comb count cats in Treatment Groups 4 and 8.
21	Infest cats in all treatment groups with approximately 100 fleas.
21 plus 4 hr.	Comb count cats in Treatment Groups 2 and 6.
21 plus 8 hr.	Comb count cats in Treatment Groups 3 and 7.
21 plus 12 hr.	Comb count cats in Treatment Groups 4 and 8.
21 plus 24 hr.	Comb count cats in Treatment Groups 1 and 5.
28	Infest cats in all treatment groups with approximately 100 fleas.
28 plus 4 hr.	Comb count cats in Treatment Groups 2 and 6.
28 plus 8 hr.	Comb count cats in Treatment Groups 3 and 7.
28 plus 12 hr.	Comb count cats in Treatment Groups 4 and 8.
28 plus 24 hr.	Comb count cats in Treatment Groups 1 and 5.
35	Infest cats in all treatment groups with approximately 100 fleas.
35 plus 4 hr.	Comb count cats in Treatment Groups 2 and 6.
35 plus 8 hr.	Comb count cats in Treatment Groups 3 and 7.
35 plus 12 hr.	Comb count cats in Treatment Groups 4 and 8.
36 (35 plus 24 hr.)	Comb count cats in Treatment Groups 1 and 5.
42	Infest cats in all treatment groups with approximately 100 fleas.
42 plus 8 hr.	Comb count cats in Treatment Groups 3 and 7.
42 plus 12 hr.	Comb count cats in Treatment Groups 4 and 8.
43 (42 plus 24 hr.)	Comb count cats in Treatment Groups 1 and 5.
44 (42 plus 48 hr.)	Comb count cats in Treatment Groups 2 and 6.

List the treatments including untreated control :

Treatment Group	Dose Rate	Study Days for Flea Infestations and Comb Counts*	
		Infestations	Comb Counts
1 (Trt. Code H)	0.7 ml of Spinetoram 11.2% (w/w) applied on Study Day 0	-1, 7, 14, 21, 28, 35, and 42	0.5 hour (+15min) after Day 0 treatment and 24 hours (± 30 min) after Day 42 infestation
2 (Trt. Code C)	0.7 ml of Spinetoram 11.2% (w/w) applied on Study Day 0	-1, 7, 14, 21, 28, 35, and 42	4 hours (± 30 min) after Day 0 treatment and 48 hours (± 30 min) after Day 42 infestation
3 (Trt. Code F)	0.7 ml of Spinetoram 11.2% (w/w) applied on Study Day 0	-1, 7, 14, 21, 28, 35, and 42	8 hours (± 30 min) after Day 0 treatment and Day 42 infestation
4 (Trt. Code D)	0.7 ml of Spinetoram 11.2% (w/w) applied on Study Day 0	-1, 7, 14, 21, 28, 35, and 42	12 hours (± 30 min) after Day 0 treatment and Day 42 infestation
5 (Trt. Code G)	0.7 ml of Vehicle Control applied on Study Day 0	-1, 7, 14, 21, 28, 35, and 42	0.5 hour (+15min) after Day 0 treatment and 24 hours (± 30 min) after Day 42 infestation
6 (Trt. Code E)	0.7 ml of Vehicle Control applied on Study Day 0	-1, 7, 14, 21, 28, 35, and 42	4 hours (± 30 min) after Day 0 treatment and 48 hours (± 30 min) after Day 42 infestation
7 (Trt. Code A)	0.7 ml of Vehicle Control applied on Study Day 0	-1, 7, 14, 21, 28, 35, and 42	8 hours (± 30 min) after Day 0 treatment and Day 42 infestation
8 (Trt. Code B)	0.7 ml of Vehicle Control applied on Study Day 0	-1, 7, 14, 21, 28, 35, and 42	12 hours (± 30 min) after Day 0 treatment and Day 42 infestation

*This interim report only includes results for Day 0 and Day 44 flea comb counts.

Number of replicates per treatment: 6

Number of individuals per replicate: 1

Length of exposure to treatment (time in seconds, minutes or hours): 44 days

Were tested specimens transferred to clean containers? NA

Experimental conditions (state relative humidity, temperature, and photoperiod): Laboratory conditions with a 12:12 light:dark cycle

Data or endpoints collected/recorded: Live fleas counts at 0.5, 4, 8, and 12 hours and on Day 0 and Day 44

Data analysis: Mean (geometric) live flea counts

RESULTS

As shown in Tables 2 and 3, the test product was very effective with > 90% kill at 8 hours which continued to Day 44.

Table 3. Day 0 Geometric Mean Live Flea Counts and Calculated Percent Efficacy

Treatment Group	Dose Rate	Flea Comb Count Timing Post-Treatment	Geo. Mean Live Flea Count	% Efficacy (GM)
1 (Trt. Code H)	0.7 ml of Spinetoram	0.5 hour	64.0	14.6
5 (Trt. Code G)	0.7 ml of Control	0.5 hour	74.9	NA
2 (Trt. Code C)	0.7 ml of Spinetoram	4 hours	59.8	20.1
6 (Trt. Code E)	0.7 ml of Control	4 hours	74.9	NA
3 (Trt. Code F)	0.7 ml of Spinetoram	8 hours	3.1	95.3
7 (Trt. Code A)	0.7 ml of Control	8 hours	66.7	NA
4 (Trt. Code D)	0.7 ml of Spinetoram	12 hours	0.0	100
8 (Trt. Code B)	0.7 ml of Control	12 hours	80.7	NA

Table 4. Day 44 Geometric Mean Live Flea Counts and Calculated Percent Efficacy

Treatment Group	Dose Rate	Flea Comb Count Timing Post-Treatment	Geo. Mean Live Flea Count	% Efficacy (GM)
2 (Trt. Code C)	0.7 ml of Spinetoram	48 hours	1.9	97.5
6 (Trt. Code E)	0.7 ml of Control	48 hours	74.7	NA

Study Author's Conclusions

The test material starts killing fleas within 30 minutes after treatment and achieved > 95% efficacy by 8 hours and continued to provide excellent control for at least 44 days.

Reviewer's Conclusions

The test material provides fast acting flea control which continued through Day 44. Control data were acceptable. No deviations from protocol were noted. Results for individual cats were not provided.

Reviewer's Recommendations

The study is acceptable and supports the fast action label claims as well as one treatment prevents further flea infestations for up to 7 weeks.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

72642-RN: Similarity to 72642-9 and DER for MRID 48875805 (pilot companion animal [8-week-old kittens] safety study with solvents)

December 27, 2012

MEMORANDUM:

Subject: Name of Pesticide Product: SPINETORAM 11.2% CAT
EPA Reg. No. /File Symbol: 72642-RN
DP Barcode: 404877
Decision No: 466770
Action Code: R310
PC Code: 110009 (Spinetoram, minor component)
110008 (Spinetoram, major component)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
Dec. 27, 2012

To: Samantha Hulkower/Mark Suarez RM 13
Insecticide Branch
Registration Division (7505P)

M. Haslam
T.L. TOXICOLOGY

Registrant: ELANCO ANIMAL HEALTH

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>by wt.</u>
110008 & 110009 Spinetoram (CAS# 187166-40-1 & 187166-15-0)	11.2%
<u>Other Ingredient(s):</u>	88.8%
Total:	100.0%

ACTION REQUESTED: "Please review the acute tox data submitted to support the registration of a new cat spot on product. This product is substantially similar to 72642-9. MRID 48875803 is also being cited...[for the companion animal data]."

BACKGROUND: The material received includes a cover letter (dated June 28, 2012) from the registrant in which it is stated that this is a me-too topical product containing spinetoram to control flea infestations on cats and kittens eight weeks and older. The product specified as similar is EPA Reg. No. 72642-9 (which has a label declaration of 39.6% spinetoram). The material also includes a label (which indicates the proposed product is packaged in 0.77 mL applicators), a CSF and citations to MRIDs 48875803 and 48875805. MRID 48875805 consists of a pilot study (not a full companion animal safety study) in 8-week-old kittens utilizing 3 formulations that consisted of combinations of solvents (but no active ingredient).

COMMENTS AND RECOMMENDATIONS:

1. In the identification of the control substances in the pilot topical study (page 3 of the confidential attachment to MRID 48875805) the percentages of the [inert] ingredients for each of the three formulations are not reported, and, for formulations A and C, the second ingredient is not fully indicated (since the ingredients reported for formulation B appear to at least partially correspond with what is present in 72642-RN, we can consider the study in MRID 48875805 as partially relevant).
2. EPA Reg. No. 72642-9 has a label declaration of 39.6% spinetoram, while EPA File Symbol 72642-RN has a label declaration of 11.2% spinetoram. EPA Reg. No. 72642-9 is packaged in 0.019 fl. oz. (0.57 mL) applicators, which will deliver 0.5 mL of the formulation; 72642-RN will be in 0.026 fl. oz. (0.77 mL) applicators [which would presumably deliver approximately 0.7 mL of the formulation]. As noted on page 6 of MRID 48875803 the amount of spinetoram applied to each cat or kitten will be reduced from 210 mg to approximately 90 mg.
3. After comparing the CSFs for 72642-9 and 72642-RN, TRB concludes that the companion animal (cat and 8-week-old kitten) safety studies in MRIDs 47899910, 47899911 and 47899912 (with additional data in MRID 48161301) used to support the registration of 72642-9 will also support the use of 72642-RN on cats and kittens (8 weeks old and older), taking into consideration the lack of significant adverse effects in a pilot topical study (MRID 48875805) in 8-week-old kittens.

EPA Reviewer: Byron T. Backus, Ph.D.
Risk Manager (EPA): 13

Date: December 27, 2012

The following table is the Data Evaluation Record (DER) for the pilot topical companion animal safety study in 8 week old kittens in MRID 48875805:

1. DP BARCODE: 404877				
2. PC CODES: n.a. (study used inert ingredients)				
3. CURRENT DATE: December 27, 2012				
4. TEST MATERIALS: Combinations of [possible?] solvents for a spinetoram spot-on for cats/kittens.				
Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Companion animal safety / 8- week old kitten MPI Research Inc., Mattawan, MI Lab. Study No. 130-256 / February 2, 2012 OCSPP 870.7200	48875805	There were six groups, each consisting of 2M & 2F 8 week old kittens, and 3 formulations (each a mixture of solvents). On Day 1, Group 1 was tested at 1X (0.8 mL) with formulation A; Group 2 was tested with 5X (4.0 mL) formulation A; Group 3 with 1X of formulation B; Group 4 with 5X of formulation B; Group 5 with 1X of formulation C and Group 6 with 5X of formulation C. Kittens were observed for 7 days. Ataxia was observed in one Group 2 kitten (5XA) at ~1 hour after treatment. Salivation was observed ~15 minutes postdose in two kittens in the Group 4 (5XB) and white frothy emesis was seen in one 1XA female ~15 minutes postdose. Scratching of the application site was observed during the first 3 hours following dosing in some kittens in 5XA, 1XC and 5XC. There were no mortalities or other effects.	n/a	S

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BAR CODE NO.: 404875 EPA File Symbol NO.: 72642-RN DECISION NO.: 466770
PC Code(s): 110009,110008 ACTION CODE: R310
FOOD Use: No

DATE OUT: December 27, 2012

SUBJECT: End Use Product Chemistry Review
Product Name: Spinetoram 11.2% Cat

FROM: Hari Mukhoty
Product Chemistry Team
Technical Review Branch / Registration Division (7505P)

TO: Samantha Hulkower, CRM / Mark Suarez PM - 13
Insecticide Branch / Registration Division (7505P)

Company Name: Elanco Animal Health.
Formulation Type: Not provided by Registrant

INTRODUCTION:

The registrant has submitted one basic CSF (Dated: 12/06/2012) and proposed a product specific label for the registration of the aforesaid product under EPA File Symbol No. 72642-RN. The registrant submitted product chemistry data under MRID(s): 488758-01, and -02.

TRB has been requested to evaluate the product chemistry data required for registration of the proposed basic product.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Spinetoram (11.2%) [Two forms: Jform - CAS # 187166-40-1 & L form - 187166-15-0]
2. Has the registrant claimed substantial similarity to registered product?
[X] Yes [] No [] NA If yes: EPA Reg. No. 72642-9
3. The source material(s) of the active ingredient(s) is/are registered with the Agency.
4. All inert ingredients have been screened by IIAB on 07/10/2012 and have been approved for non-food use.
5. The CSF of the proposed basic has been filled out completely but not correctly.

DP BAR CODE NO.: 404875 EPA File Symbol NO.: 72642-RN DECISION NO.: 466770
PC Code(s): 110009,110008 ACTION CODE: R310
FOOD Use: No

6. Confidential Statement of Formula(s):

☒ Basic - Dated: 06/12/2012 re-submitted - Dated: NA
☐ Alternate Dated: re-submitted: Dated: NA

Alternate CSF(s) complies with 40CFR §152.43: ☐ Yes ☐ No NA ☒. Alternate CSF is not acceptable for other changes needed to become acceptable.

7. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2)

☒ Yes

Is the sub statement in compliance with PR Notice 97-6?

☒ Yes ☐ No - Uses the term "Other Ingredients"
, if not, explain below:

Metallic equivalent: ☐ Yes ☒ NA
Soluble arsenic: ☐ Yes ☒ NA
Isomeric ratios: ☐ Yes ☒ NA Spinetoram is a fermentation product containing two closely related active ingredients: XDE-175-J and XDE-175-L (3:1 ratio (J: L)).
Acid equivalent: ☐ Yes ☒ NA

b. Health related sub statements:

Petroleum distillate at > 10%: ☐ Yes ☐ No ☒ NA
Methanol at > 4%: ☐ Yes ☐ No ☒ NA
Sodium Nitrate / Sodium Nitrite ☐ Yes ☐ No ☒ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Total Release Fogger PR Notice 98-6 (40 CFR 156.78 d): ☐ Yes ☐ No ☒ NA

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No

Final decision of overall label acceptance will be made by the PM.

DP BAR CODE NO.: 404875 EPA File Symbol NO.: 72642-RN DECISION NO.: 466770
 PC Code(s): 110009,110008 ACTION CODE: R310
 FOOD Use: No

8. Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos. 488758-02
			Yes	No		
830.1550	Product Identity & Composition			X	G	"
830.1600	Description of materials used to produce the product			X	G	"
830.1650	Description of formulation process			X	G	"
830.1670	Discussion on the formation of impurities			X	G	"
830.1700	Preliminary analysis				NR	CSF dated 06/12/2012
830.1750	Certified limits (158.350)	Standard certified Limits				
		Justification for wider limits		X	Not provided	
830.1800	Enforcement analytical method #		X		A**	488758-02

A = Acceptance, NR = Not Required, G = Data Gap,
 W = Waiver Request, I = In Progress, NA = Not Acceptable
 # Analytical Method: HPLC using UV detector set at 250 nm. ** Validation was performed for precision, linearity and accuracy.

Chem:

DP BAR CODE NO.: 404875 EPA File Symbol NO.: 72642-RN DECISION NO.: 466770
PC Code(s): 110009,110008 ACTION CODE: R310
FOOD Use: No

9. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos. 488758-01
830.6303	Physical State	Liquid	A	"
830.6315	Flammability	Flash Point is 111.1° C (231.8° F)	A	"
830.6316	Explosibility	Contains no explosive component	A	"
830.7000	pH	6.50 & water used had a pH of 5.74	A	"
830.7300	Density	1.1621 g/ml	A	"

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress.

CONCLUSIONS:

1. TRB has reviewed the CSF (dated: 12/06/2012) for the proposed basic and has found it to be unacceptable because (a) no Group A data, with the exception of enforcement analytical method used and validation data, have been provided to TRB. The CSF is attached with this review and can be located in OPPIN CHEM DOCS.
2. Substantial similarity between the proposed product and the cited product (EPA Reg. No. 72642-9) shall be determined when the proposed product becomes acceptable.
3. No Group A data, with the exception of enforcement analytical method used and validation data, have been provided to TRB. TRB did contact the applicant over the phone and did not receive any response. Group B data, with the exception of Storage stability (830.6317) and Corrosion Characteristics (630.6320) are satisfied and acceptable.
4. The registrant must generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is required that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in electronic and hard copy format.
5. The proposed label was screened as it pertains to the product chemistry requirements. The PM should get the "Formulation Type" from the registrant. The preferred site would be on the proposed label under "Direction to Use". The final review of the proposed label and uses are the purview of the PM team.



RE: Follow up on EPA file symbol number 72642-RN

Katherine E Vannatta

to:

Mark Suarez, Driss Benmhend

01/04/2013 10:29 AM

Cc:

Joseph R Winkle, Aaron Edward Johnson, Katherine A Meyer

Hide Details

From: Katherine E Vannatta <vannatta_katherine_e@elanco.com>

To: Mark Suarez/DC/USEPA/US@EPA, Driss Benmhend/DC/USEPA/US@EPA

Cc: Joseph R Winkle <winkle_joseph_r@elanco.com>, Aaron Edward Johnson <ajohnson@elanco.com>, Katherine A Meyer <meyer_katherine_a@elanco.com>

*One of Samontha's
Ser Jkr & files*

1 Attachment



image002.gif

Mark-

Thank you for your note.

As we've returned from our winter break, we realized Katie received some questions from the product chemistry reviewer that are still unresolved. We believe he has returned his review as "rejected" with 2 outstanding issues. 1) Related to the certified limits and needing a justification for being outside the normal range provided in the CFR and 2) needing a statement that no chemical reaction is taking place during the formulation process, so that the formula does not differ from the composition of formula.

We do not understand the reviewer's first concern as we have double checked the certified limits provided on the CSF ; we believe it may be due to interpretation on the rounding of the +/- 5% on the active ingredient. We would be happy to fix this and send you a revised CSF if this is the case. We also can provide the statement requested relative to the formulation. Please let me know how we can either address these items now so the review and registration can continue on-time, or how we might be able to quickly address these issues as part of the conditional registration.

Please do not hesitate to contact me if you have questions or concerns.

Kathy

Kathy Vannatta
Senior Director
Companion Animal Product Development
Office 317-277-3362
Mobile 317-997-0188



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From: Suarez.Mark@epamail.epa.gov [<mailto:Suarez.Mark@epamail.epa.gov>]

Sent: Monday, December 31, 2012 11:10 AM

To: Katherine E Vannatta

Subject: Re: Follow up on EPA file symbol number 72642-RN

Kathy,

Thank you for letting us know what constraints you are facing. We certainly appreciate that you, and other registrants, face deadlines that hinge upon our decisions. The PRIA due date is 20 January 2013. As that is a Sunday, a regulatory decision (barring negotiating a new PRIA due date) will be made on or before 18 January 2013. Providing an electronic copy of the SAL should not be a problem.

Regards,
 Mark

Mark E. Suarez, Product Manager 13
 Insecticide Branch
 Registration Division (7505P)
 Office of Pesticide Programs
 Environmental Protection Agency
 1200 Pennsylvania Avenue, NW
 Washington, DC 20460

(703)305-0120
suarez.mark@epa.gov

▼ Katherine E Vannatta ---12/19/2012 05:55:47 PM---Mark and Driss- I wanted to follow up on some email correspondences between you and my colleague, Ms

From: Katherine E Vannatta <vannatta_katherine_e@elanco.com>
 To: Driss Benmhend/DC/USEPA/US@EPA, Mark Suarez/DC/USEPA/US@EPA
 Cc: Joseph R Winkle <winkle_joseph_r@elanco.com>, Cory T Herr <herr_cory_t@elanco.com>
 Date: 12/19/2012 05:55 PM
 Subject: Follow up on EPA file symbol number 72642-RN

Mark and Driss-

I wanted to follow up on some email correspondences between you and my colleague, Ms Katie Meyer regarding the ongoing review of application 72642-RN. Katie is out of the office with the upcoming winter break. We appreciate all that EPA is going to prioritize the completion of the review of our application and requesting that the scientific reviews be given priority. We recognize that you cannot commit to a timeframe earlier than the PRIA date, but were hoping you could clarify the official PRIA date. By our calculation it would be late January or early February. We are seeking clarification, not only for the planning purposes of our client owned study that Katie mentioned in her email, but also for planning on the manufacture of the end product. The current manufacturing site has notified us that they will no longer manufacture our product after March 1 and as you can imagine we are working with them closely to ensure the manufacturing and the appropriate labeling of the product so we can conduct the study and meet the anticipated commercial needs for 2013. With registration expected in the late January/early February timeframe, this is a very tight timeline.

Therefore, we have 2 requests of EPA

- 1) Can you share with us the PRIA due date?
- 2) As soon as the stamped EPA label is available if it could be faxed or emailed to us so we do not lose unnecessary time awaiting it via post office mail? You may forward the stamped label directly to me, my contact information is listed below.

If you feel a short phone call is merited, we'd be available still before the end of the year or right after the new year. Please don't hesitate to contact me with any questions or concerns.

Thank You!
Kathy

Kathy Vannatta
Senior Director
Global Companion Animal Product Development
Office 317-277-3362
Mobile 317-997-0188
Fax 317-277-4755

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This Email message contained an attachment named image001.jpg which may be a computer program. This attached computer program could contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced into the EPA network. EPA is deleting all computer program attachments sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, you should contact the sender and request that they rename the file name extension and resend the Email with the renamed attachment. After receiving the revised Email, containing the renamed attachment, you can rename the file extension to its correct name.

For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

***** ATTACHMENT NOT DELIVERED *****

***** ATTACHMENT NOT DELIVERED *****

This Email message contained an attachment named
image001.jpg

which may be a computer program. This attached computer program could contain a computer virus which could cause harm to EPA's computers, network, and data. The attachment has been deleted.

This was done to limit the distribution of computer viruses introduced into the EPA network. EPA is deleting all computer program attachments sent from the Internet into the agency via Email.

If the message sender is known and the attachment was legitimate, you should contact the sender and request that they rename the file name extension and resend the Email with the renamed attachment. After receiving the revised Email, containing the renamed attachment, you can rename the file extension to its correct name.

For further information, please contact the EPA Call Center at (866) 411-4EPA (4372). The TDD number is (866) 489-4900.

***** ATTACHMENT NOT DELIVERED *****

DATA PACKAGE BEAN SHEET

Date: 28-Aug-2012

Page 1 of 2

Decision #: 466770

DP #: (404877)

PRIA

Parent DP #:

Submission #: 921585

E-Sub #:

*** Registration Information ***

Registration: 72642-RN - SPINETORAM 11.2% CAT

Company: 72642 - ELANCO ANIMAL HEALTH

Risk Manager: RM 13 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246

Risk Manager Reviewer: Samantha Hulkower SHULKOWE

Sent Date: 03-Aug-2012

PRIA Due Date: 20-Jan-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 110009, Spinetoram (minor component (4-methyl))(0%)

110008, Spinetoram (major component (4,5-dihydro))(0%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 28-Aug-2012

Due Back: _____

DP Ingredient: 110008, Spinetoram (major component (4,5-dihydro))

110009, Spinetoram (minor component (4-methyl))

DP Title: Companion animal data for new spot on

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 21-Dec-2012

Team Name: TOX

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Please review the acute tox data submitted to support the registration of a new cat spot on product. This product is substantially similar to 72642-9. MRID 48875803 is also being cited for the acute tox data.

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48875800		Elanco Animal Health (2012) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Spinetoram 11.2% Cat. Transmittal of 8 Studies.		Pass (14-Aug-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.1200/Acute dermal toxicity	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.1300/Acute inhalation toxicity	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.2400/Acute eye irritation	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.2500/Acute dermal irritation	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.2600/Skin sensitization	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.7200/Companion animal safety	Pass (19-Jul-2012)
48875805		Lloyd, Z. (2012) Companion Animal Safety: Control Substances: A Pilot Topical Study in 8-Week Old Kittens. Project Number: 130/256. Unpublished study prepared by MPI Research, Inc. 129p.	870.7200/Companion animal safety	Pass (19-Jul-2012)

DATA PACKAGE BEAN SHEET

Date: 28-Aug-2012

Page 1 of 2

Decision #: 466770

DP #: (404876)

PRIA

Parent DP #:

Submission #: 921585

E-Sub #:

*** Registration Information ***

Registration: **72642-RN - SPINETORAM 11.2% CAT**

Company: 72642 - ELANCO ANIMAL HEALTH

Risk Manager: RM 13 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246

Risk Manager Reviewer: Samantha Hulkower SHULKOWE

Sent Date: 03-Aug-2012

PRIA Due Date: 20-Jan-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 110009, Spinetoram (minor component (4-methyl))(0%)

110008, Spinetoram (major component (4,5-dihydro))(0%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 28-Aug-2012

Due Back: _____

DP Ingredient: 110008, Spinetoram (major component (4,5-dihydro))

110009, Spinetoram (minor component (4-methyl))

DP Title: Acute tox data for new spot on

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 21-Dec-2012

Team Name: TOX

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Please review the acute tox data submitted to support the registration of a new cat spot on product. This product is substantially similar to 72642-9. MRID 48875803 is also being cited for the companion animal data.

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48875800		Elanco Animal Health (2012) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Spinetoram 11.2% Cat. Transmittal of 8 Studies.		Pass (14-Aug-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.1200/Acute dermal toxicity	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.1300/Acute inhalation toxicity	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.2400/Acute eye irritation	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.2500/Acute dermal irritation	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.2600/Skin sensitization	Pass (19-Jul-2012)
48875803		Winkle, J. (2012) Bridging Rationale: Companion Animal Safety/Toxicology. Unpublished study prepared by Elanco Animal Health. 33p.	870.7200/Companion animal safety	Pass (19-Jul-2012)
48875804		Hadd, S. (2012) Toxicology: Primary Eye Irritation of Spinetoram 11.2%: (Rabbit). Project Number: 130/266. Unpublished study prepared by MPI Research, Inc. 54p.	870.2400/Acute eye irritation	Pass (19-Jul-2012)

DATA PACKAGE BEAN SHEET

Date: 28-Aug-2012

Page 1 of 2

Decision #: 466770

DP #: (404875)

PRIA

Parent DP #:

Submission #: 921585

E-Sub #:

*** Registration Information ***

Registration: **72642-RN - SPINETORAM 11.2% CAT**

Company: 72642 - ELANCO ANIMAL HEALTH

Risk Manager: RM 13 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246

Risk Manager Reviewer: Samantha Hulkower SHULKOWE

Sent Date: 03-Aug-2012

PRIA Due Date: 20-Jan-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 110009, Spinetoram (minor component (4-methyl))(0%)

110008, Spinetoram (major component (4,5-dihydro))(0%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 28-Aug-2012

Due Back: _____

DP Ingredient: 110008, Spinetoram (major component (4,5-dihydro))

110009, Spinetoram (minor component (4-methyl))

DP Title: Product chemistry for pending spot on

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / TRB

Last Possible Science Due Date: 21-Dec-2012

Team Name: CHEM

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Please review the product chemistry data submitted to support the registration of a new cat spot on product. This product is substantially similar to 72642-9.

DP#: (404875)

*** Studies Sent for Review ***

Decision#: (466770)

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48875800		Elanco Animal Health (2012) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Spinetoram 11.2% Cat. Transmittal of 8 Studies.		Pass (14-Aug-2012)
48875801		Elliott, T. (2012) Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation. Project Number: 68064. Unpublished study prepared by ABC Laboratories, Inc. 26p.	830.6302/Color	Pass (14-Aug-2012)
48875801		Elliott, T. (2012) Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation. Project Number: 68064. Unpublished study prepared by ABC Laboratories, Inc. 26p.	830.6303/Physical state	Pass (14-Aug-2012)
48875801		Elliott, T. (2012) Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation. Project Number: 68064. Unpublished study prepared by ABC Laboratories, Inc. 26p.	830.6304/Odor	Pass (14-Aug-2012)
48875801		Elliott, T. (2012) Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation. Project Number: 68064. Unpublished study prepared by ABC Laboratories, Inc. 26p.	830.6314/Oxidizing or reducing action	Pass (14-Aug-2012)
48875801		Elliott, T. (2012) Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation. Project Number: 68064. Unpublished study prepared by ABC Laboratories, Inc. 26p.	830.6315/Flammability	Pass (14-Aug-2012)
48875801		Elliott, T. (2012) Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation. Project Number: 68064. Unpublished study prepared by ABC Laboratories, Inc. 26p.	830.7000/pH	Pass (14-Aug-2012)
48875801		Elliott, T. (2012) Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation. Project Number: 68064. Unpublished study prepared by ABC Laboratories, Inc. 26p.	830.7100/Viscosity	Pass (14-Aug-2012)
48875801		Elliott, T. (2012) Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation. Project Number: 68064. Unpublished study prepared by ABC Laboratories, Inc. 26p.	830.7300/Density/relative density	Pass (14-Aug-2012)
48875802		Elliott, T. (2012) Product Chemistry: Enforcement Method and Validation for the Quantitation of 11.2% wt/wt Spinetoram J and L in Formulation. Project Number: 68306. Unpublished study prepared by ABC Laboratories, Inc. 59p.	830.1800/Enforcement analytical method	Pass (14-Aug-2012)

DATA PACKAGE BEAN SHEET

Date: 28-Aug-2012

Page 1 of 2

Decision #: 466770

DP #: (404873)

PRIA

Parent DP #:

Submission #: 919462

E-Sub #:

*** Registration Information ***

Registration: **72642-RN - SPINETORAM 11.2% CAT**

Company: 72642 - ELANCO ANIMAL HEALTH

Risk Manager: RM 13 - Mark Suarez - (703) 305-0120 Room# PY1 S-7246

Risk Manager Reviewer: Samantha Hulkower SHULKOWE

Sent Date: _____

PRIA Due Date: 20-Jan-2013

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R310) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST

Ingredients: 110008, Spinetoram (minor component (4-methyl))(0%)

110008, Spinetoram (major component (4,5-dihydro))(0%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 28-Aug-2012

Due Back: _____

DP Ingredient: 110008, Spinetoram (major component (4,5-dihydro))

110008, Spinetoram (minor component (4-methyl))

DP Title: Efficacy for new spot on

CSF Included: ☐ Yes ☒ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: RD / IB

Last Possible Science Due Date: 21-Dec-2012

Team Name: Efficacy (IB)

Science Due Date: _____

Reviewer Name: _____

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Please review the efficacy data submitted to support the registration of a new cat spot on product. This product is substantially similar to 72642-9.

MRID	MRID Status	Citation Reference	Guideline	86-5 Status
48875800		Elanco Animal Health (2012) Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of Spinetoram 11.2% Cat. Transmittal of 8 Studies.		Pass (14-Aug-2012)
48875806		Everett, W. (2012) Product Performance: Efficacy of Spinetoram 11.2% (w/w) Topical Formulation Against Cat Fleas on Adult Cats. Project Number: GN58S120009. Unpublished study prepared by BerTek, Inc. 32p.	810.3300/Treatments to control pests of humans and pets	Pass (19-Jul-2012)
48875807		Young, D. (2012) Product Performance: Efficacy of Spinetoram 11.2% (w/w) Topical Formulation Against Cat Fleas on Adult Cats. Project Number: B6FUS120001. Unpublished study prepared by Young Veterinary Research Services. 32p.	810.3300/Treatments to control pests of humans and pets	Pass (19-Jul-2012)
48875808		Everett, W. (2012) Knockdown and Speed of Kill Effectiveness of Spinetoram 11.2% (w/w) Topical Formulation Administered to Cats for the Treatment of Cat Fleas and its Residual Efficacy: Interim Report. Project Number: B6FUS120002. Unpublished study prepared by BerTek, Inc. 30p.	810.3300/Treatments to control pests of humans and pets	Pass (19-Jul-2012)

Decision Information for 72642-RN

Decision Seq: 466770
Action Code: R310, NEW PRODUCT; NON-FAST TRACK (INCLUDES REVIEWS)

Decision Status

Tracking

Create Resubmission

FFS Letters

Waiver Documentation

Action Code History

Secondary Decision

FFS Start Date: 20-Jul-2012
Tentative Ind: No
FFS Original Decision:

Due Date: 20-Jan-2013
75-Day Due Date:
FFS EUP Decision:

OPP Target Due Dt:
21-Day Screen Dt: 20-Jul-2012
FFS Primary Decision:

Negotiated Due Dt:
Start/Stop Clock
FGPA Clock:

Registrant:
Days Elapsed:

Response Due Date:
Current Status: PENDING (05-Jul-2012)

Decision Comments
Payment
Unmatched Payments
75 Day Letters

Meetings & Milestones
FFS Information
FFS Negotiated Due Dates
OPP Target Due Date

Decision Ownership
Receipts
Data Package
Reduced Risk

Receipts	Staff Member	Reg/DCI Number	Submission Due Dt	Response
S: 921585	Hulkower, Samantha	72642-RN	20-Jan-2013	PENDING
NA				
S: 919462	Hulkower, Samantha	72642-RN	20-Jan-2013	PENDING
Cat spot-on				

Viewing Record 1 of 1



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 8, 2012

ELANCO ANIMAL HEALTH
2500 INNOVATION WAY
PO.BOX: 708
GREENFIELD, IN 46140

Report of Analysis for Compliance with PR Notice 11-3

Thank you for your submittal of 03-AUG-2012. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-3. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 921585

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Pending Product Amendment

Billable: ☐ Yes ☒ No

Company: 72642 ELANCO ANIMAL HEALTH

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 13

Product #: 72642-RN

Product Name: SPINETORAM 11.2% CAT

Override#:

Me Too

Section3: 72642-9

Me Too

Product Name: ASSURITY CAT

Application Date: 28-Jun-2012

ie

OPP Rec'd Date: 03-Aug-2012

ie

Front End Date: 03-Aug-2012

ie

Risk Manager Send Date: 03-Aug-2012

ie

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Des

Study

<

>

Fast Track: ☐

New Ingredient: ☐

View/Edit

Receipt Description:

application for pesticide registration

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt for Section 3					
S:	919462	Resubmission:	<input type="radio"/> Yes	<input checked="" type="radio"/> No	<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input checked="" type="radio"/> Yes	<input type="radio"/> No	
Application Type:	New Registration	Billable:	<input checked="" type="radio"/> Yes	<input type="radio"/> No	
Company:	72642 ELANCO ANIMAL HEALTH			V	
Risk Manager:	Registration Division, Risk Management Team 13				
Product #:	72642-RH	Product Name:	SPINETORAM 11.2% CAT		
Override#:					
Me Too Section3:	72642-9	Me Too Product Name:	ASSURITY CAT		
Application Date:	28-Jun-2012	OPP Rec'd Date:	29-Jun-2012		
Front End Date:	02-Jul-2012	Risk Manager Send Date:			
FFS Due Date:		Negotiated Due Date:			
OPP Target Date:					
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>		
Receipt Description:		View/Edit			
Application for pesticide registration		<div>New Ingredient Request Date</div> <div>New Ingredient Received Date</div>			
Form A:	<input type="checkbox"/>	Signature Date:		Form B:	<input type="checkbox"/>
		Signature Date:			

Memorandum

Date: 07/19/12

To: PM 13, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☐ fully accepted submission
☒ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 13, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

ELANCO ANIMAL HEALTH
2500 INNOVATION WAY
PO.BOX : 708
GREENFIELD, IN 46140

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 29-JUN-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 11-3, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document. Please use these numbers in all future reference to these documents. Some individual documents were not acceptable. The rejected studies and their deficiencies are described below.

48875801

* The presence of a Confidential Attachment causes a direct conflict with the No Claim of Confidentiality statement.

48875802

* The presence of a Confidential Attachment causes a direct conflict with the No Claim of Confidentiality statement.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 13, 2012

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

ELANCO ANIMAL HEALTH
2500 INNOVATION WAY
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GREENFIELD, IN 46140

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 29-JUN-12. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 11-3, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document. Please use these numbers in all future reference to these documents. Some individual documents were not acceptable. The rejected studies and their deficiencies are described below.

48875801

* The presence of a Confidential Attachment causes a direct conflict with the No Claim of Confidentiality statement.

48875802

* The presence of a Confidential Attachment causes a direct conflict with the No Claim of Confidentiality statement.

Spinetoram 11.2% Cat
Master Label

Page 1 of 25

Marketing claims: see lists at the end of the draft labels.
Alternative language in (parentheses)

CARTON LABELFRONT PANEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.

Picture of Cat or Kitten

ACTIVE INGREDIENT

Spinetoram (CAS# 187166-40-1 & 187166-15-0) 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN**CAUTION**

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12 -- 0.026 fl oz (0.77 ml) applicator

BACK PANEL**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION****HAZARDS TO HUMANS**

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID**IF IN EYES:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No.

PACKAGE INSERT LABEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID**IF IN EYES:**

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- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for further manufacture or repacking of a registered pesticide product for companion animals.

Read the entire label, directions for use and frequency of application each time before using this product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between the shoulder blades. Avoid getting the product in your pet's eyes or mouth.

Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)

6. Discard empty applicator tube in the trash.

Picture/drawing
of opening the
tube.

Picture/drawing
of parting the
hair on neck at
base of head.

Picture/drawing
of applying the
product.

Monthly application is recommended to prevent and treat flea infestations. Spinetoram 11.2% Cat starts working in 30 minutes, kills adult fleas before the lay eggs and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE

Page 7 of 25

USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No.

Applicator Labeling

Spinetoram 11.2% Cat
Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

Spinetoram 11.2% Cat
Spinetoram 11.2%

For Cats and Kittens 8 weeks of age (and older)

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Spinetoram 11.2% Cat for cats and kittens 8 weeks of age and older.

Visit www.elanco.com to sign up and receive an email reminder from your cat when it is time to receive Spinetoram 11.2% Cat.

Graphic of calendar

Month 1 (Graphic)	Month 2 (Graphic)	Month 3 (Graphic)	Month 4 (Graphic)	Month 5 (Graphic)	Month 6 (Graphic)
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Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [*Ctenocephalides felis*] on cats (and kittens) 8 weeks of age or older only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- Kills fleas before they lay eggs
- Kills adult fleas before they lay eggs
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective for up to 7 weeks
- (Long Lasting) one treatment prevents further flea infestations for up to 7 weeks
- (Long Lasting) one treatment remains effective for up to 7 weeks
- (Long Lasting) one treatment kills fleas and prevents reinfestation for up to 7 weeks
- (Long Lasting) remains effective through 6 weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- Long-lasting flea control for up to 7 weeks
- Long-lasting flea control through 6 weeks
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)

- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Spinetoram 11.2% Cat, is a member of the spinosyn class of pesticide
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8 weeks of age (and older) only
- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control and prevention of fleas
- Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)

Spinetoram 11.2% Cat
Sub-Label #1 Residential

Page 13 of 25

Marketing claims: see lists at the end of the draft labels.
Alternative language in (parentheses)

CARTON LABELFRONT PANEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

Marketing claims: see lists at the end of the draft labels.

Picture of Cat or Kitten

ACTIVE INGREDIENT

Spinetoram (CAS# 187166-40-1 & 187166-15-0) 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN**CAUTION**

SEE BACK PANEL FOR PRECAUTIONARY STATEMENTS

READ ALL DIRECTIONS BEFORE USING THIS PRODUCT

CONTENTS

1, 2, 3, 4, 6, 8, 12 – 0.026 fl oz (0.77 ml) applicator

BACK PANEL**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

More detailed directions for use are included in the box. Read the entire label, directions for use and frequency of application each time before using this product.

For prevention and treatment of fleas, part the hair on the neck at the base of the head and apply the contents of the applicator tube to a single spot on the skin of the cat. Do not apply on the surface of the cat's hair coat. Place the empty applicator tube in the trash.

Monthly application is recommended to prevent and treat flea infestations. Spinetoram 11.2% Cat starts working in 30 minutes, kills adult fleas before they lay eggs and continues killing fleas for a full month after application.

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION****HAZARDS TO HUMANS**

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetance have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

FIRST AID**IF IN EYES:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

Manufactured for

Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No.

PACKAGE INSERT LABEL

Spinetoram 11.2% Cat

spinetoram

A ONCE-A-MONTH TOPICAL SOLUTION FOR THE PREVENTION AND TREATMENT OF
FLEA INFESTATIONS

ONLY FOR CATS AND KITTENS EIGHT WEEKS OF AGE (AND OLDER)

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.2%

OTHER INGREDIENTS 88.8%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS – CAUTION

HAZARDS TO HUMANS

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Avoid contact with eyes or clothing.

HAZARDS TO DOMESTIC ANIMALS

FOR USE ON CATS AND KITTENS ONLY. For external use only. Do not use on kittens less than eight (8) weeks of age. Do not allow your cat to ingest this product. Use only a single dose on cats weighing greater than 20 lbs. As with any product, consult your veterinarian before using the product on debilitated, aged, pregnant or nursing animals or animals known to be sensitive to pesticides.

SIDE EFFECTS:

Monitor your cat after application. Side effects may include signs of application site reactions such as application site hair loss, hair change (greasy, clumping or matting) or redness, inflammation and itching. Other side effects such as inactivity, vomiting and inappetence have also been reported. If these or any other side effects occur, consult your veterinarian, your cat's healthcare expert. For technical assistance or to report a side effect, call Elanco at 1-888-545-5973.

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- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read the entire label, directions for use and frequency of application each time before using the product. For external use on cats and kittens only.

FREQUENCY OF APPLICATION

To kill fleas and prevent reinfestations, apply to cats and kittens 8 weeks of age and older as follows:

HOW TO APPLY

1. Use only on cats and kittens 8 weeks of age and older and weighing 1.8 lbs or more. Do not use more than a single dose on cats weighing greater than 20 lbs.
2. Remove one applicator tube from the blister package.
3. Hold applicator tube in an upright position.
4. Press cap down until it clicks (indicating the tube has been punctured). Hold upright and remove cap. Check to be sure there is an opening at the tip of tube.
5. Part the hair on the neck at the base of the head until the skin is visible. Place the tip of the tube directly above the skin and squeeze the tube 2-4 times to expel the contents of the tube directly on the skin. For best results, apply at the base of the head, not between shoulder blades. Avoid getting the product in your pet's eyes or mouth. Treatment at the base of the head will minimize the opportunity for the cat to directly lick the product. Do not allow your cat to ingest this product. (There may be a small residual remaining in the tube after a full dose is expelled.)
6. Discard empty applicator tube in the trash.

Picture/drawing
of opening the
tube.

Picture/drawing
of parting the
hair on neck at
base of head.

Picture/drawing
of applying the
product.

Monthly application is recommended to prevent and treat flea infestations. Spinetoram 11.2% Cat starts working in 30 minutes, kills adult fleas before they lay eggs and continues killing fleas for a full month after application.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage:

Store in original package in a cool dry place.

Pesticide Disposal:

Call your local solid waste agency or 1-800-CLEANUP or equivalent organization for disposal instructions. Unless otherwise instructed place in trash. Never pour unused product down the drain or on the ground.

Container Handling:

If empty: Non-refillable container. Do not reuse this container. Place in the trash, or offer for recycling if available.

If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

LIMITED WARRANTY AND LIMITATIONS OF LIABILITY

By using, buying or handling this product, users or buyers accept the following conditions, disclaimer of warranties and limitations of liability. The directions for use of this product are believed to be adequate and must be followed carefully. All risks of product use or handling are assumed by the user or buyer. No agent of Elanco is authorized to make, extend or modify any warranties. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW ELANCO MAKES NO OTHER WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. ELANCO DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. To the extent consistent with applicable law the exclusive remedy of the user or buyer for any and all losses, injuries or damages resulting from the use or handling of this product, whether in contract, warranty, tort, negligence, strict liability or otherwise, is limited to the purchase price paid or replacement of the product.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No.

Applicator Labeling

Spinetoram 11.2% Cat
Spinetoram 11.2%

Cats and Kittens 8 weeks & older

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

Blister Labeling

Spinetoram 11.2% Cat
Spinetoram 11.2%

For Cats and Kittens 8 weeks of age (and older)

0.026 fl oz (0.77 mL)

EPA Reg. No 72642-RN

CAUTION
Keep Out of Reach of Children

Read Entire Label Before Use

ELANCO

Lot No.

(Calendar) Reminder Stickers

Place stickers on your calendar as a reminder to apply Spinetoram 11.2% Cat for cats and kittens 8 weeks of age and older.

Visit www.elanco.com to sign up and receive an email reminder from your cat when it is time to receive Spinetoram 11.2% Cat.

Graphic of calendar

Month 1 (Graphic)	Month 2 (Graphic)	Month 3 (Graphic)	Month 4 (Graphic)	Month 5 (Graphic)	Month 6 (Graphic)
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Optional Marketing Claims

- Once-a-month
- Topical
- Topical Solution
- Single topical (spot-on) application
- For the prevention and treatment of flea infestations [*Ctenocephalides felis*] on cats (and kittens) 8 weeks of age or older only
- Kills fleas
- (Fast Acting) kills fleas on cats within 8 hours
- (Fast Acting) starts killing fleas in 30 minutes
- (Fast Acting) starts working in 30 minutes
- Kills fleas which may cause flea allergy dermatitis (FAD)
- Kills fleas before they lay eggs
- Kills adult fleas before they lay eggs
- (Long Lasting) one treatment prevents further flea infestations through 6 weeks
- (Long Lasting) one treatment remains effective through 6 weeks
- (Long Lasting) remains effective for up to 7 weeks
- (Long Lasting) one treatment prevents further flea infestations for up to 7 weeks
- (Long Lasting) one treatment remains effective for up to 7 weeks
- (Long Lasting) one treatment kills fleas and prevents reinfestation for up to 7 weeks
- (Long Lasting) remains effective through 6 weeks
- Fragrance-free
- Quick-drying
- Non-greasy
- Formulated (exclusively) for cats and kittens 8 weeks of age (and older)
- Kills fleas that may carry and transmit *Rickettsia felis* and *Rickettsia typhi*, *Francisella tularensis*
- Kills fleas that may carry and transmit bartonellosis, tapeworm and tularemia
- For indoor and outdoor cats and kittens
- Kills fleas that may cause anemia
- Long-lasting flea control for up to 7 weeks
- Long-lasting flea control through 6 weeks
- The primary target of action of spinetoram on insects is an activation of nicotinic acetylcholine receptors (nAChRs).
- Spinetoram does not interact with known insecticidal binding sites of other nicotinic or GABAergic insecticides such as neonicotinoids, fiproles, milbemycins, avermectins, and cyclodienes.
- Insects in contact with spinetoram show involuntary muscle contractions and tremors resulting from activation of motor neurons.
- Prolonged spinetoram-induced hyperexcitation results in prostration and paralysis resulting in death of fleas.
- Topical application
- One size for all cats/ kittens 8 weeks of age and older only.
- One (applicator tube, size, package, dose, treatment, application) treats all (any) size(s) of cats and kittens 8 weeks of age and older only.
- 6 Pack
- Single Pack (Single dose, individual dose)

- Topical flea treatment
- Convenient
- Easy to apply (easy to use)
- Spinetoram, the active ingredient in Spinetoram 11.2% Cat, is a member of the spinosyn class of pesticide
- Protects cats and kittens 8 weeks of age (and older) (all sizes) from fleas (for one month)
- One size application is effective for all (any) sizes (weight ranges) of cats and kittens 8 weeks of age (and older) only
- (Flea infestations may vary) Monthly treatment (year-round) is recommended for optimal control and prevention of fleas
- Satisfaction Guaranteed (Call 1-888-545-5973 if you have any questions.)

Spinetoram 11.2% Cat
Sub-label #2 Commercial

Page 24 of 25

(label to be placed near discharge control valve, this statement can be removed from printed label)

Spinetoram 11.2% Cat

spinetoram

ACTIVE INGREDIENT

Spinetoram [CAS# 187166-40-1 & 187166-15-0] 11.20%

OTHER INGREDIENTS 88.80%

TOTAL 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

PRECAUTIONARY STATEMENTS**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Avoid contact with eyes or clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID**IF IN EYES:**

- Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

IF SWALLOWED:

- Call a poison control center or doctor immediately for treatment advice. Have the product label with you when you call the poison control center or medical professional.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact Rocky Mountain Poison Control at 1-888-767-5023 for emergency medical treatment information.

DIRECTIONS FOR USE:

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

General use pesticide. For use only for the further manufacture or repacking of a registered pesticide product for companion animals.

STORAGE AND DISPOSAL:

Do not contaminate water, food or feed by storage and disposal.

Pesticide Storage: Store in original package only. In case of leak or spill, contain material with absorbent materials and dispose as waste.

Pesticide Disposal: Waste resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Never pour unused product down the drain or on the ground.

Container Handling: Refillable container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents into manufacturing process or appropriate waste collection system. Fill the container about 10% full with water, and if possible, spray all sides while adding water. If practical, agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into a waste collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by other procedures allowed by state and local authorities.

Manufactured for
Elanco Animal Health
A Division of Eli Lilly and Company
Indianapolis, IN 46285

EPA Reg. No. 72642-RN
EPA Est. No. 70996-CAN-002

NET CONTENTS: _____
(may be completed by manual entry)

APPLICATION TO REGISTER SPINETORAM 11.2% Cat

A once monthly topical for the prevention and treatment of flea infestation on cats and kittens,
eight weeks and older.

End Use Product
EPA FILE SYMBOL 72642-RN

VOLUME 72642-9-RN-1CA
ADMINISTRATIVE VOLUME
CONFIDENTIAL ATTACHMENT

DATA REQUIREMENTS
Guideline Numbers: 40 CFR 152.42 and 40 CFR 152.50

AUTHOR
Katherine A. Meyer

DATE COMPLETED
June 28, 2012

SPONSOR
Elanco Animal Health
A Division of Eli Lilly & Company
2500 Innovation Way
Greenfield, IN 46140

PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 6-29-12 ^{3/23/09}

Experts In-Processing Signature: B. R. Date 7-6-12 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>72642-RN</u>		EPA Receipt Date: <u>6-29-12</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form) a) All inerts (link to http://www.epa.gov/opprd001/inerts/), including fragrances, approved for the proposed uses (see Footnote A)			X		
		yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)		yes	no		
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)		yes	no		
			X			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to http://www.epa.gov/oppfead1/labeling/lrm/) (Electronic labels on CD are encouraged and guidance is available)(link to http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels)			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)		X	
8	Notice of Filing (link to http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm) included with petitions (link to http://www.epa.gov/pesticides/regulating/tolerances.htm)			X
9	If applicable for conventional applications, reduced risk rationale (link to http://www.epa.gov/opprd001/workplan/reducedrisk.html)			X
10	Required Data (link to http://www.epa.gov/pesticides/regulating/data_requirements.htm) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- Inerts approved for nonfood use
- active ing. not added in oppin (not specified on label / CSF)
- Registrant contacted on 07/11, 07/12, 07/13 for study deficiencies:
study 01 and 02: nonconfidential statement (pg. 2) causes a direct conflict w/conf. attachment
- Registrant was out of the office until 07/13, no corrections sent yet
- * Due to time constraints on our part, we are failing the studies. Corrections underway according to registrant.

Studies fail
jacket pass
JB 07/13/12

MRID: 488758

Draft rejection letter in H:/ drive (draft rejection folder).

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to http://www.epa.gov/oppbppd1/biopesticides/contacts_bppd.htm].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Script for Rejection Phone calls

Contact Name: Katherine Meyer
Phone #: 317-433-2167
Email: meyer-katherine-a@elanco.com

First Call/Initials:

Date: 07/11/12, 07/12
Time:

Second Call/Initials:

Date:
Time:

This is _____, EPA contractor.

I'm calling regarding your submission in support of

Spinoram 11.2% CAT (72642-RN).

We have found the following deficiencies regarding:

PR Notice 86.5: Yes or No

Volume/Study Title:

Study 01 : nonconf. statement (pg 2) and conf. attachment

Volume/Study Title:

Study 02 :

Volume/Study Title:

Additional volumes continued on back of page: Yes or No

Application Package: Yes or No

These deficiencies have been approved by EPA.

The corrections can be faxed to 703-305-5060/Attn: _____.

Second Call/Email:

If we do not receive the corrections by _____, we will process your submission, accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.



EPA Submission: Spinetoram 11.2% Cat (EPA Registration Number :
72642-RN)

Jennifer Brandon to: meyer_katherine_a
Cc: Sree Nair

07/13/2012 10:00 AM

Ms. Meyer,

This is a follow up email to my correspondence sent on 07/11/12, with regards to your application for the product **Spinetoram 11.2% Cat (72642-RN)**. I have made several attempts to reach you at 317-433-2167. Due to time constraints on my part, I will be sending the application and studies directly to the PM. Please send all study corrections to the corresponding PM.

Thanks,

Jennifer Brandon
Data Analyst (EPA Contractor)
2777 S. Crystal Drive
Arlington, VA 22202
Ph: 703-305-0074
Fax: 703-305-5060
Email: brandon.jennifer@epa.gov

— Forwarded by Jennifer Brandon/DC/USEPA/US on 07/13/2012 09:58 AM —

From: Jennifer Brandon/DC/USEPA/US
To: meyer_katherine_a@elanco.com
Cc: Sree Nair/DC/USEPA/US@EPA
Date: 07/11/2012 09:19 AM
Subject: EPA Submission: Spinetoram 11.2% Cat (EPA Registration Number: 72642-RN)

Ms. Meyer

This is a follow- up email with regard to your submission in support of the product **Spinetoram 11.2% Cat (EPA Registration Number: 72642-RN)**. We have found the following deficiencies regarding the studies submitted with your application:

Study 01: Vol. #: 72642-RN-2

Study 02: Vol. #: 72642-RN-3

The presence of a Confidential Attachment causes a direct conflict with the No Claim of Confidentiality Statement on page 2 of the study.

You can send the study corrections by email to brandon.jennifer@epa.gov.

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or NO (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis		✓				
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor	✓					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	✓					
830.6315	Flammability	✓					
830.6316	Explosibility	N/A					
830.6317	Storage stability	N/A					
830.6319	Miscibility	N/A					
830.6320	Corrosion Characteristics	N/A					
830.6321	Dielectric Breakdown Voltage	N/A					
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	✓					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 5, 2012

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-466770
EPA File Symbol or Registration Number: 72642-RN
Product Name: SPINETORAM 11.2% CAT
EPA Receipt Date: 29-Jun-2012
EPA Company Number: 72642
Company Name: ELANCO ANIMAL HEALTH

KATHERINE A. MEYER
ELANCO ANIMAL HEALTH
A DIVISION OF ELI LILLY AND COMPANY
2500 INNOVATION WAY
GREENFIELD, IN 46140

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee
Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Downs".

Front End Processing Staff

Information Technology & Resources Management Division

Fee for Service

{9194624~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

13

Receipt No.

S- 919462

EPA File Symbol/Reg. No.

72642-RN

Pin-Punch Date:

6/29/2012

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R310

Granted: R310

Amount Due: \$ 4.807

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: S. Hill

Date: 7/2/12

Remarks:

Receipt for Section 3					
S:	919462		Resubmission:	<input type="radio"/> Yes <input checked="" type="radio"/> No	
Regulatory Type:	Product Registration - Section 3		Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Application Type:	New Registration		Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No	
Company:	72642 ELANCO ANIMAL HEALTH		V		
Risk Manager:	Registration Division, Risk Management Team 13				
Product #:	72642-RH	Product Name:	SPINETORAM 11.2% CAT		
Override#:					
Me Too Section3:	72642-9	Me Too Product Name:	ASSURITY CAT		
Application Date:	28-Jun-2012	OPP Rec'd Date:	29-Jun-2012		
Front End Date:	02-Jul-2012	Risk Manager Send Date:			
FFS Due Date:		Negotiated Due Date:			
OPP Target Date:					
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>		
Receipt Description:				View/Edit	
Application for pesticide registration				New Ingredient Request Date: New Ingredient Received Date: Form A: <input type="checkbox"/> Signature Date: Form B: <input type="checkbox"/> Signature Date:	

Print Letter
 Enter More Information
 Tracking

Receipt Content
 Study
 CSF

FEE FOR SERVICE

Pay.gov - Online Payment

Page 1 of 1

Online Payment

Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees

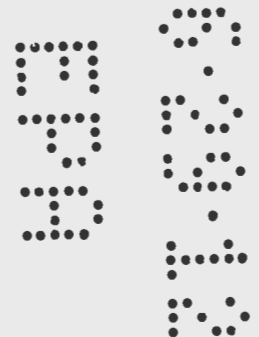
Pay.gov Tracking ID: 2573LTDJ

Agency Tracking ID: 74326930868

Transaction Date and Time: 06/22/2012 11:06 EDT

Payment Summary


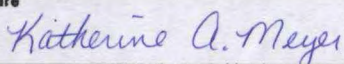
Address Information	Account Information	Payment Information
Account Holder Daniel R Name: Engleking 2500 Innovation Billing Address: Way Billing Address 2: City: Greenfield State / Province: IN Zip / Postal Code: 46140 Country: USA	Card Type: Visa Card Number: *****2058 Decision Number: Registration Number: Company Elanco Animal Name: Health Company Number: 72642 Action Code: R310	Payment Amount: \$4,807.00 Transaction Date 06/22/2012 and Time: 11:06 EDT



Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060

Print Form

		United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide - Section I					
1. Company/Product Number Elanco Animal Health / EPA File No. 72642-RN		2. EPA Product Manager Mark Suarez		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
4. Company/Product (Name) Spinetoram 11.2% Cat		PM# 13			
5. Name and Address of Applicant (Include ZIP Code) Elanco Animal Health, A Division of Eli Lilly & Company 2500 Innovation Way, Greenfield, IN 46140 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>72642-9</u> Product Name <u>Assurity (L899 Insecticide)</u>			
Section - II					
<input type="checkbox"/> Amendment - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____			
<input type="checkbox"/> Resubmission in response to Agency letter dated _____		<input checked="" type="checkbox"/> "Me Too" Application.			
<input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Other - Explain below.			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) PRIA Category: R310 Agency Tracking ID: 74326930868 Pay.gov Tracking ID: 2573LTDJ					
Section - III					
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. 0.026fl oz	No. per container see below	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 1,2,3,4,6,8,12 x Applicators		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input checked="" type="checkbox"/> Other product insert			
Section - IV					
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Katherine A. Meyer		Title Associate Consultant		Telephone No. (Include Area Code) 317-433-2167	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Associate Consultant, Regulatory Affairs			
4. Typed Name Katherine A. Meyer		5. Date Jun 27, 2012			



Elanco Animal Health
A Division of Eli Lilly and Company

2500 Innovation Way
PO Box 708
Greenfield, IN 46140

(317) 276-2000

Mr. Mark Suarez
Product Manager #13
U.S. EPA – OPP – RD – IB
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

June 28, 2012

SUBJECT: Application for pesticide registration of a reduced risk RTU once a month topical for the prevention and treatment of flea infestation on cats and kittens, eight weeks and older.

COMPANY: Elanco Animal Health, A Division of Eli Lilly and Company, 2500 Innovation Way, Greenfield, IN 46104

CONTACT: Katherine A. Meyer
Associate Consultant – Regulatory Affairs
Elanco Animal Health
A Division of Eli Lilly and Company
2500 Innovation Way
Greenfield, IN 46140

PRIA: R 310
Fee Paid on: June 22, 2012
Agency tracking ID: 74326930868

PRODUCT: Spinetoram 11.2% Cat [EPA File Symbol 72642-RN]

Dear Mr. Suarez:

On behalf of Elanco Animal Health, I submit for your review and approval this application to register a substantially similar ("me-too") topical product containing spinetoram for the prevention and treatment of flea infestations on cats and kittens eight weeks and older (similar to Assurity – EPA Reg. # 72642-9).

In addition to this letter, this volume (Volume 1) contains:

- Application for pesticide registration [8570-1]
- Formulator's Exemption [8570-27]
- Certification with respect to data citation [8570-34]

- Data matrix [8570-35]
- Draft label (5 copies); one bound into this volume and four loose
- Confidential Statement of Formula [8570-4]

Please note: There are 2 producers listed on the Confidential Statement of Formula (Form 8570-4) due to the need to register a bulk container from the formulator and also the final commercial product in the applicator tubes.

In addition to Volume 1, the Spinetoram 11.2% Cat application consists of the following (3 copies each):

VOLUME 72642-RN-2	Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation (ABC Study No. 68064)
VOLUME 72642-RN-3	Enforcement Method and Validation for the Quantitation of 11.2% wt/wt Spinetoram J and L in Formulation (ABC Study No. 68306)
VOLUME 72642-RN-4	Bridging Rationale for Companion Animal Safety and Toxicology Requirements between Assurity and Spinetoram 11.2% Cat
VOLUME 72642-RN-5	Primary Eye Irritation of Spinetoram 11.2% (MPI Study No. 130-266)
VOLUME 72642-RN-6	Companion Animal Safety: A Pilot Topical Study in 8-Week Old Kittens, Control Substances (MPI Study No. 130-256)
VOLUME 72642-RN-7	Product Performance: Efficacy of Spinetoram 11.2% (w/w) Topical Formulation Against Cat Fleas on Adult Cats (Study No. GN5US120009)
VOLUME 72642-RN-8	Product Performance: Efficacy of Spinetoram 11.2% (w/w) Topical Formulation Against Cat Fleas on Adult Cats (Study No. B6FUS120001)
VOLUME 72642-RN-9	Product Performance: Knockdown and Speed of Kill Effectiveness of Spinetoram 11.2% (w/w) Topical Formulation Administered to Cats for the Treatment of Cat Fleas and Its Residual Efficacy (Study No. B6FUS120002) [Interim Report]

Referring to the phone conference between Elanco Animal Health and your office held on March 27, 2012: In this teleconference, EPA recommended PRIA Code 310 and the path of a "me-too" (substantially similar to Assurity – EPA Reg. No. 72642-9) registration to enable the conduct of a client owned study in the fall of 2012, after registration of Spinetoram 11.2% Cat. We would like to reiterate our intent to conduct this client-owned study. There has been a reduced rate of side effects observed in the completed laboratory studies conducted to support the registration of this product. The client-owned study will evaluate the rate and type of side effects in non-laboratory animals using EPA registered product prior to commercial launch. This study is intended to demonstrate that Spinetoram 11.2% Cat has fewer side effects compared to Assurity (EPA Reg. No. 72642-9). We appreciate the agency's willingness to work with us to allow for the conduct of this study in early November 2012 to be completed in time to launch the new product for the 2013 flea season, as discussed in our phone conference.

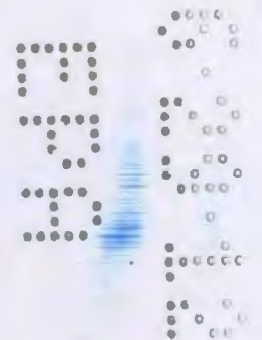
No new human health risk assessment is needed for this "me-too" use (D376415). Elanco conducted a dislodgeable residue study and submitted a revised proposal for human health risk assessment for Assurity (MRID 48595401). However, EPA should note the amount of spinetoram applied is reduced from 210 mg to approximately 90 mg with the Spinetoram 11.2% Cat product and therefore the margin of exposure to dislodgeable residues will correspondingly increase (improve). Elanco Animal Health is willing to provide revised calculations for the margin of exposure and human health risk assessment as a condition of registration if EPA would need it for further future refinements.

If you have any questions or require further information, please do not hesitate to contact me by email at meyer_katherine_a@elanco.com or by phone at 317-433-2167.

Sincerely,

Katherine A. Meyer

Katherine A. Meyer
Elanco Animal Health



Transmittal Document

SUBMITTER:

Elanco Animal Health
A Division of Eli Lilly & Company
2500 Innovation Way
Greenfield, IN 46140

Company Contact:
Typed Name of Signer:

Katherine A. Meyer
Katherine A. Meyer
Elanco Animal Health

Phone: 317-433-2167
Fax: 317-277-4755
Email address: meyer_katherine_a@elanco.com

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

APPLICATION TO REGISTER SPINETORAM 11.2% CAT

A once monthly topical for the prevention and treatment of flea infestation on cats and kittens, eight weeks and older.

TRANSMITTAL DATE:

June 28, 2012

PRIA INFORMATION:

PRIA Category: R310
Agency Tracking ID: 74326930868
Pay.gov Tracking ID: 2573LTDJ

LIST OF SUBMITTED DOCUMENTS:**VOLUME 72642-RN-1**

Administrative Volume: Application, Confidential Statement of Formula, Forms, Labels & Correspondence

VOLUME 72642-RN-2

Product Chemistry Evaluation of an 11.2% wt/wt Spinetoram Formulation (ABC Study No. 68064)

VOLUME 72642-RN-3

Enforcement Method and Validation for the Quantitation of 11.2% wt/wt Spinetoram J and L in Formulation (ABC Study No. 68306)

VOLUME 72642-RN-4	Bridging Rationale for Companion Animal Safety and Toxicology Requirements between Assurity and Spinetoram 11.2% Cat
VOLUME 72642-RN-5	Primary Eye Irritation of Spinetoram 11.2% (MPI Study No. 130-266)
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Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.



United States
Environmental Protection Agency
Washington, DC 20460
Formulator's Exemption Statement
(40 CFR 152.85)

Applicant's Name and Address Elanco Animal Health A Division of Eli Lilly and Company 2500 Innovation Way Greenfield, IN 46140	EPA File Symbol/Registration Number 72642-RN
	Product Name Spinetoram 11.2% Cat
	Date of Confidential Statement of Formula (EPA Form 8570-4) 06/12/2012

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Spinetoram Technical (86.4%)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Spinetoram J (CAS # 187166-40-1) Spinetoram L (CAS # 187166-15-0)		


Product ingredient source information may be entitled to confidential treatment

Signature <i>Katherine A. Meyer</i>	Name and Title Katherine A. Meyer	Date 06/27/2012
--	--------------------------------------	--------------------

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460		
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (282ZT), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.		
Certification with Respect to Citation of Data		
Applicant's/Registrant's Name, Address, and Telephone Number Elanco Animal Health, 2500 Innovation Way, Greenfield, IN 46140 Ph: 317-433-2187		EPA Registration Number/File Symbol 72642-RN
Active Ingredient(s) and/or representative test compound(s) Spinetoram Technical (Spinetoram J & Spinetoram L)		Date June 27, 2012
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor Non-food use		Product Name Spinetoram 11.2% Cat
NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).		
<input type="checkbox"/> I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).		
SECTION I: METHOD OF DATA SUPPORT (Check one method only)		
<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).		<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
SECTION II: GENERAL OFFER TO PAY		
[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]		
<input checked="" type="checkbox"/> I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.		
SECTION III: CERTIFICATION		
<p>I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.</p> <p>I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.</p> <p>I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.</p> <p>I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.</p> <p>I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>		
Signature <i>Katherine A. Meyer</i>	Date June 27, 2012	Typed or Printed Name and Title Katherine A. Meyer

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DATA MATRIX

Date 6/27/2012		EPA Reg No./File Symbol 72642-RN		Page 1 of 2	
Applicant's/Registrant's Name & Address Elanco Animal Health, A Division of Eli Lilly & Company, 2500 Innovation Way, Greenfield, IN 46140		Product Spinetoram 11.2% Cat			
Ingredient Spinetoram Technical (86.4%)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 830.1550	Product identity and composition	this submission	Elanco Animal Health	Own	72642-RN-2
830.1600	Description of starting materials used to make product	this submission	Elanco Animal Health	Own	72642-RN-2
830.1650	Description of the formulation process	this submission	Elanco Animal Health	Own	72642-RN-2
830.1670	Discussion of formation of impurities	this submission	Elanco Animal Health	Own	72642-RN-2
830.1750	Certified Limits	this submission	Elanco Animal Health	Own	72642-RN-2
830.1800	Enforcement Analytical Method	this submission	Elanco Animal Health	Own	72642-RN-2
830.6000/7000	Physical/chemical characteristics	this submission	Elanco Animal Health	Own	72642-RN-2
40 CFR 160.105	Test sample characterization & stability evaluation	this submission	Elanco Animal Health	Own	72642-RN-6
40 CFR 160.105	Test sample characterization & stability evaluation	this submission	Elanco Animal Health	Own	72642-RN-7
870.1100	Acute oral toxicity	47920101	Elanco Animal Health	Own	Bridged
870.1200	Acute dermal toxicity	47920102	Elanco Animal Health	Own	Bridged
870.1300	Acute inhalation toxicity	47920103	Elanco Animal Health	Own	Bridged
870.2400	Acute eye irritation	this submission	Elanco Animal Health	Own	72642-RN-5
870.2500	Acute dermal irritation	47920104	Elanco Animal Health	Own	Bridged
870.2600	Skin Sensitization	47920105	Elanco Animal Health	Own	Bridged
Signature <i>Katherine A. Meyer</i>			Name and Title Katherine A. Meyer, Associate Regulatory Consultant		Date 06/27/2012

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Elanco Animal Health

Registration of Spinetoram 11.2% Cat

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DATA MATRIX

Date 6/27/2012

EPA Reg No./File Symbol 72642-RN

Page 2 of 2

Applicant's/Registrant's Name & Address

Elanco Animal Health, A Division of Eli Lilly & Company, 2500 Innovation Way, Greenfield, IN 46140

Product

Spinetoram 11.2% Cat

Ingredient Spinetoram Technical (86.4%)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
OPPTS 870.7200	Companion Animal Safety (cats)	47899910	Elanco Animal Health	Own	Bridged
	Companion Animal Safety (kittens)	47899912	Elanco Animal Health	Own	Bridged
	Companion Animal Safety (kittens-exciplents only)	this submission	Elanco Animal Health	Own	72642-RN-6
	Bridging Rationale - Comp. Animal Safety/Toxicology	this submission	Elanco Animal Health	Own	72642-RN-4
40 CFR 159.165	Adverse Incident Report related to 72642-9 (Assurity)	47899911	Elanco Animal Health	Own	
810.3300	Product Performance	this submission	Elanco Animal Health	Own	72642-RN-7
	Product Performance	this submission	Elanco Animal Health	Own	72642-RN-8
	Product Performance	this submission	Elanco Animal Health	Own	72642-RN-9

Signature

Katherine A. Meyer

Name and Title

Katherine A. Meyer, Associate Regulatory Consultant

Date

06/27/2012



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WASHINGTON, D.C. 20460

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Applicant's/Registrant's Name & Address Elanco Animal Health, A Division of Eli Lilly & Company, 2500 Innovation Way, Greenfield, IN 46140		Product Spinetoram 11.2% Cat			
Ingredient Spinetoram Technical (86.4%)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
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			Elanco Animal Health	Own	
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			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
Signature <i>Katherine A. Meyer</i>			Name and Title Katherine A. Meyer, Associate Regulatory Consultant		Date 06/27/2012

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Elanco Animal Health

Registration of Spinetoram 11.2% Cat

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DATA MATRIX

Date 6/27/2012		EPA Reg No./File Symbol 72642-RN		Page 2 of 2	
Applicant's/Registrant's Name & Address Elanco Animal Health, A Division of Eli Lilly & Company, 2500 Innovation Way, Greenfield, IN 46140		Product Spinetoram 11.2% Cat			
Ingredient Spinetoram Technical (86.4%)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
			Elanco Animal Health	Own	
Signature <i>Katherine A. Meyer</i>			Name and Title Katherine A. Meyer, Associate Regulatory Consultant		Date 06/27/2012

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Elanco Animal Health

Registration of Spinetoram 11.2% Cat

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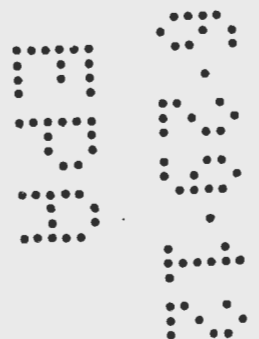
GOOD LABORATORY PRACTICES STATEMENT

The purpose and scope of this study DO NOT fall under the requirements of 40 CFR 160.

Submitter: Katherine A. Meyer Date: 28 Jun 2012

Typed Name of Signer: Katherine A. Meyer

Typed Name of Company: Elanco Animal Health



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